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DiCarlo et al.

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(54) **SURGICAL SUTURING INSTRUMENT AND METHOD OF USE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 266 days.

(21) Appl. No.: **10/440,805**

(22) Filed: **May 19, 2003**

(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation-in-part of application No. 10/352,600, filed on Jan. 28, 2003, and a continuation-in-part of application No. 10/378,805, filed on Mar. 4, 2003, and a continuation-in-part of application No. 10/396,927, filed on Mar. 25, 2003.

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(51) **Int. Cl.**
A61B 17/04 (2006.01)

(52) **U.S. Cl.** **606/144**; 606/139; 606/148

(58) **Field of Classification Search** 606/139, 606/144, 148
See application file for complete search history.

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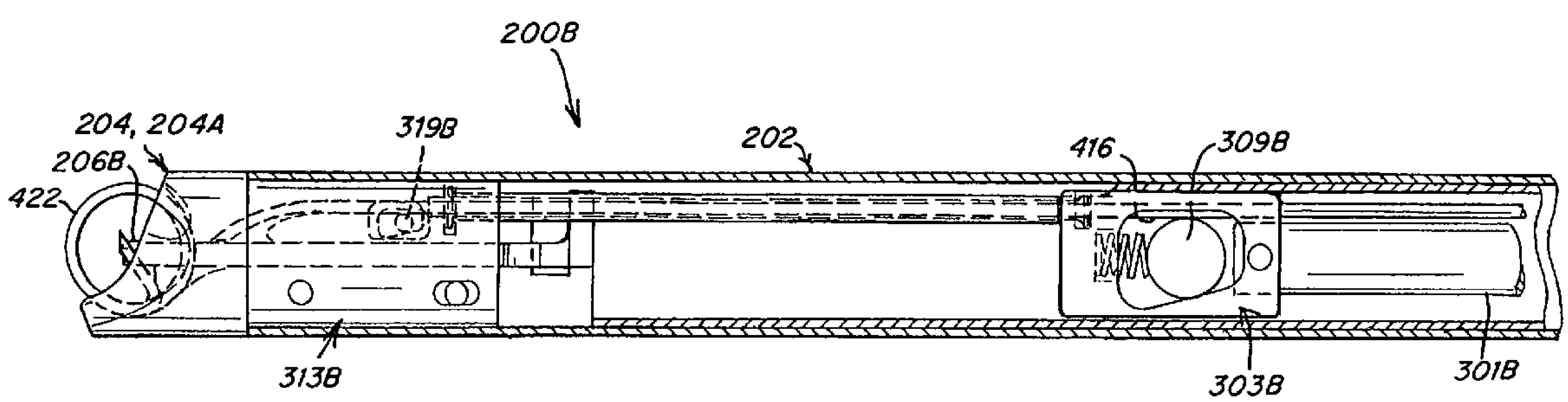
(74) *Attorney, Agent, or Firm*—Wolf, Greenfield & Sacks, P.C.

(57) **ABSTRACT**

A device is disclosed for introducing a flexible elongated element through at least two portions of a subject. The device includes an advancement unit for advancing the flexible elongated element toward the end of the device such that the elongated element may exit from the device with sufficient force to pass through the subject. The device also includes a curved die for imparting a looping configuration to portions of the flexible elongated element exiting the device, and a curved guide for receiving the looped flexible elongated element as it returns to the end of the device. A cutting mechanism is provided to permit the looped flexible elongated element to be separated from the remainder of the flexible elongated element. The cutting mechanism is adapted to deform the trailing end of the looped flexible elongated element so that the trailing end is forced distally, toward the subject being sutured.

133 Claims, 42 Drawing Sheets



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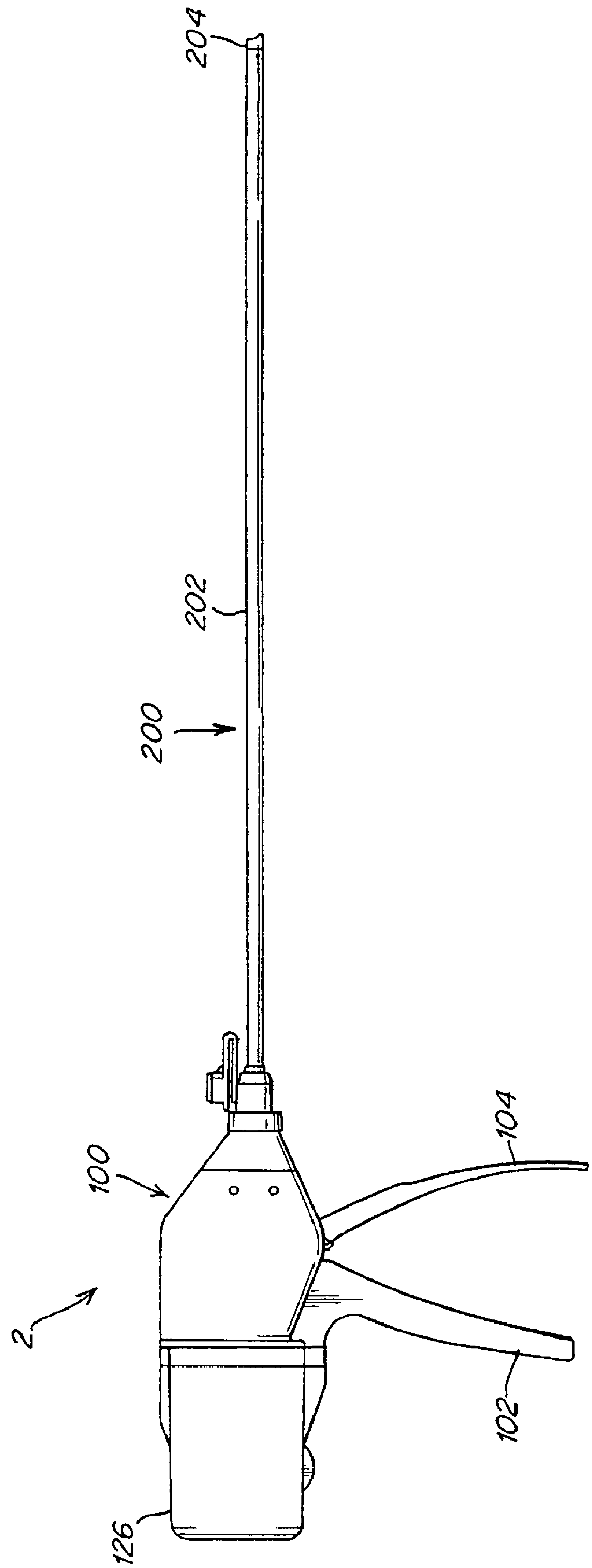

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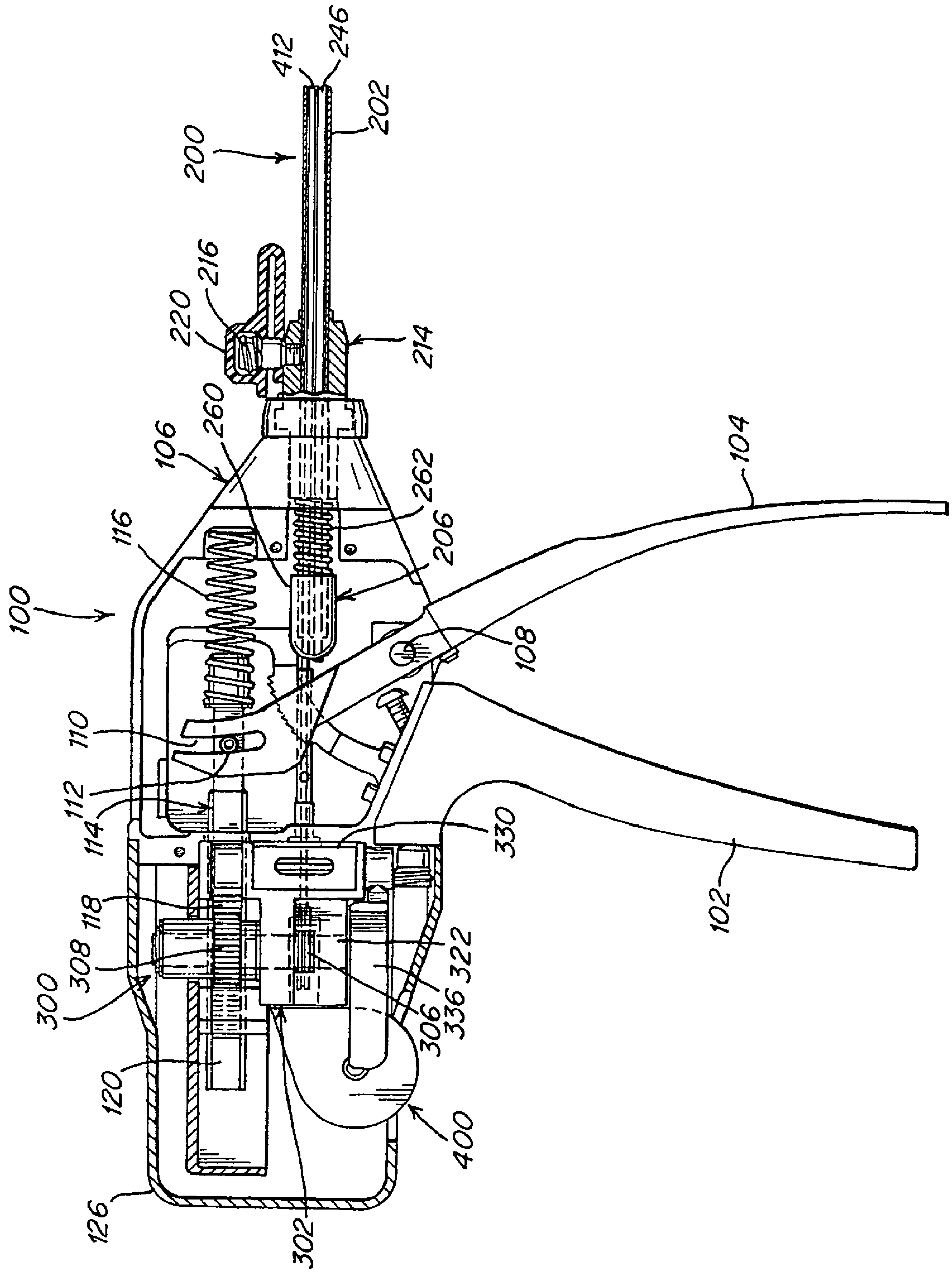
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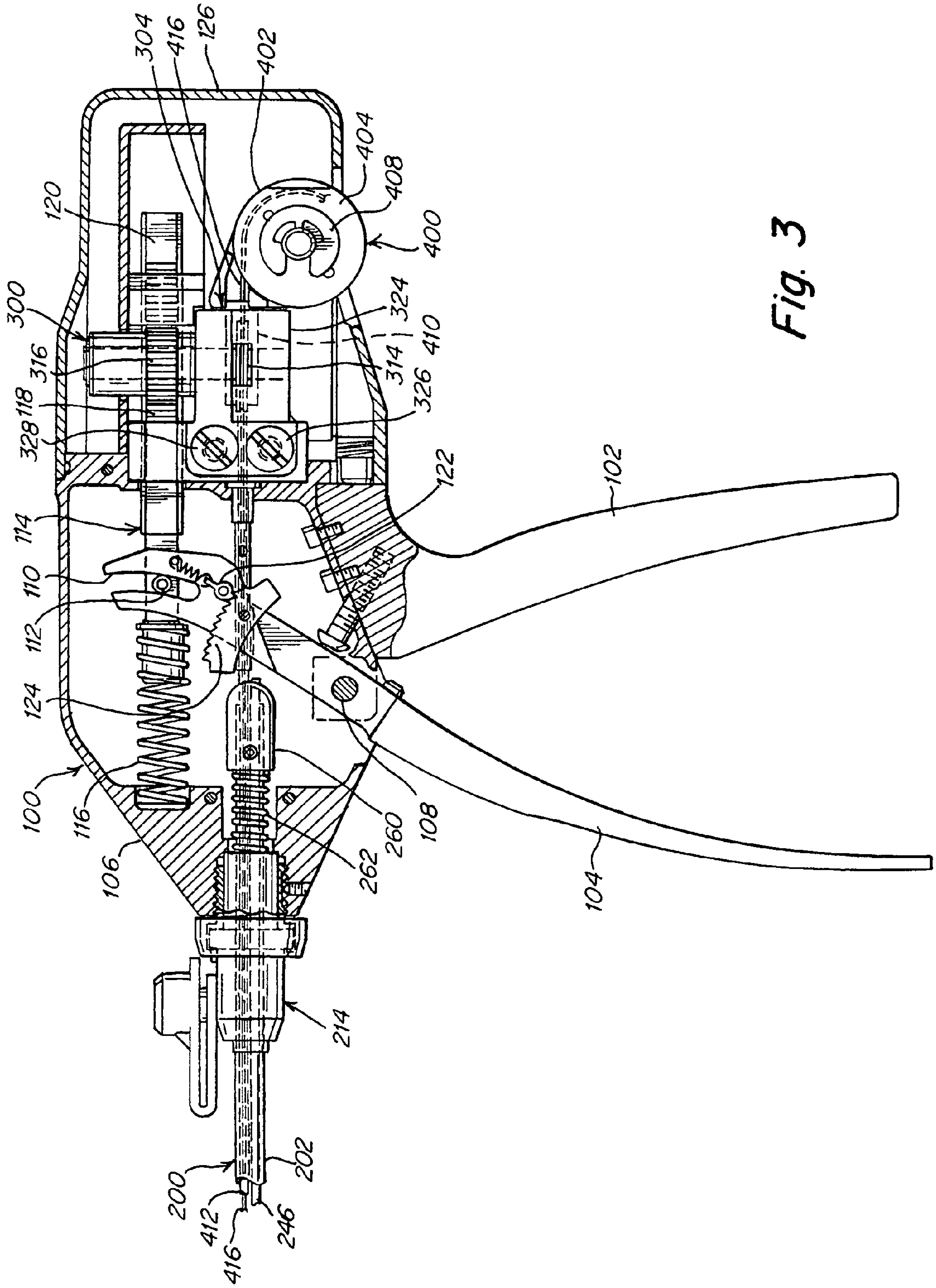
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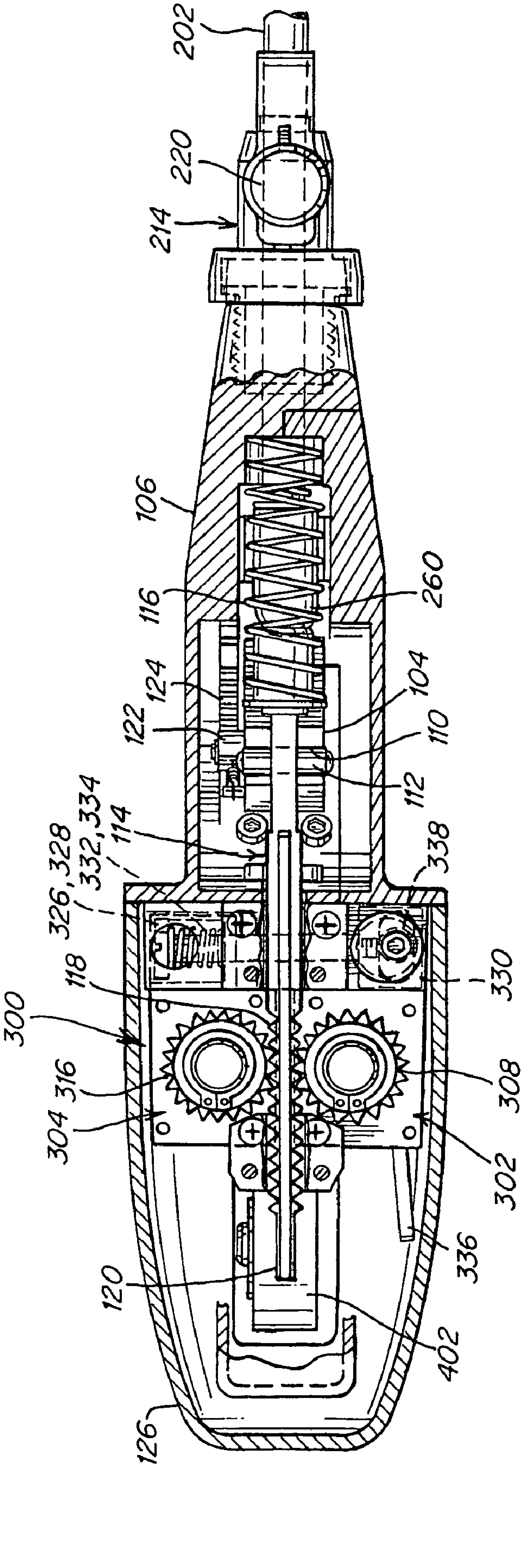
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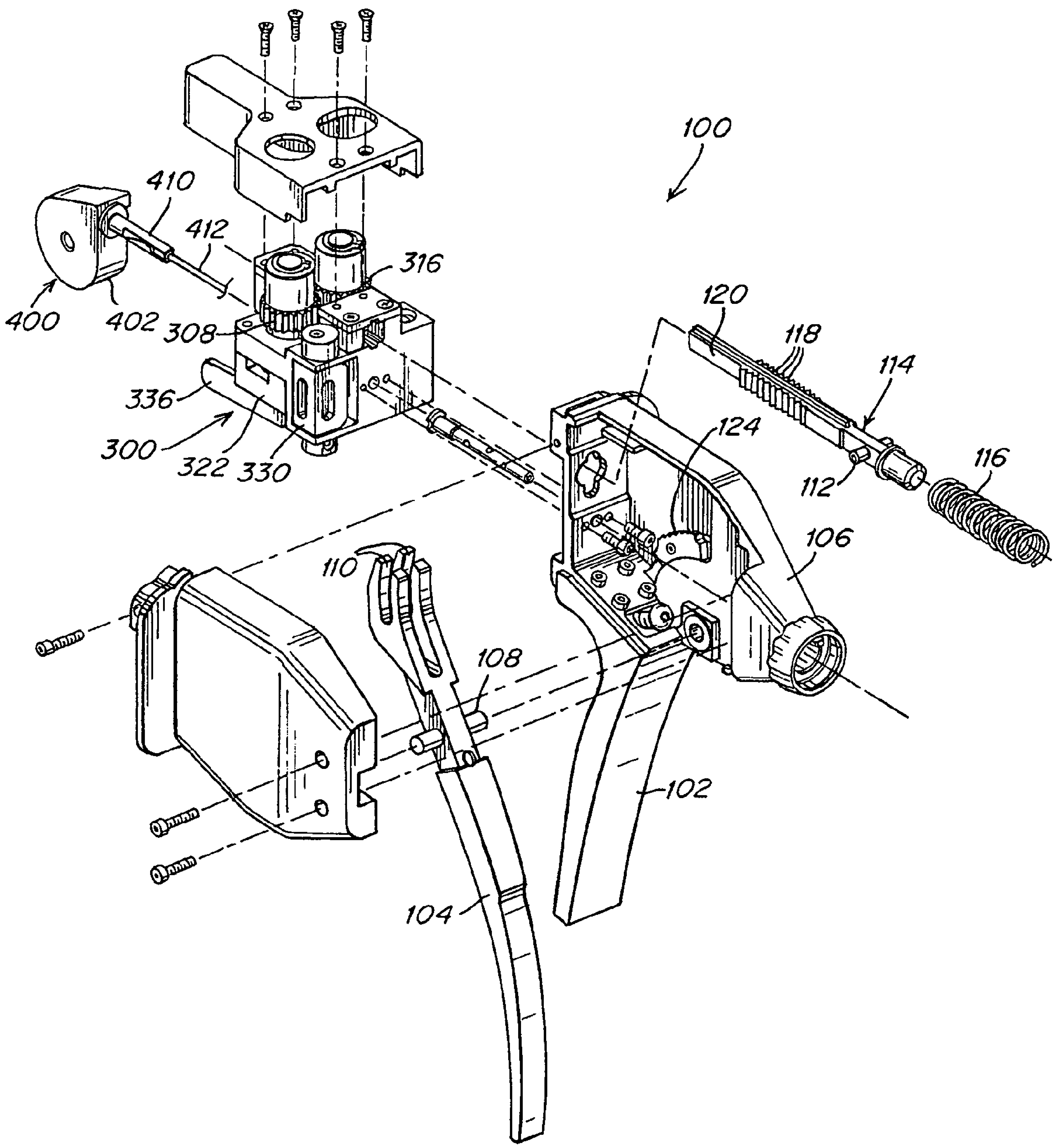
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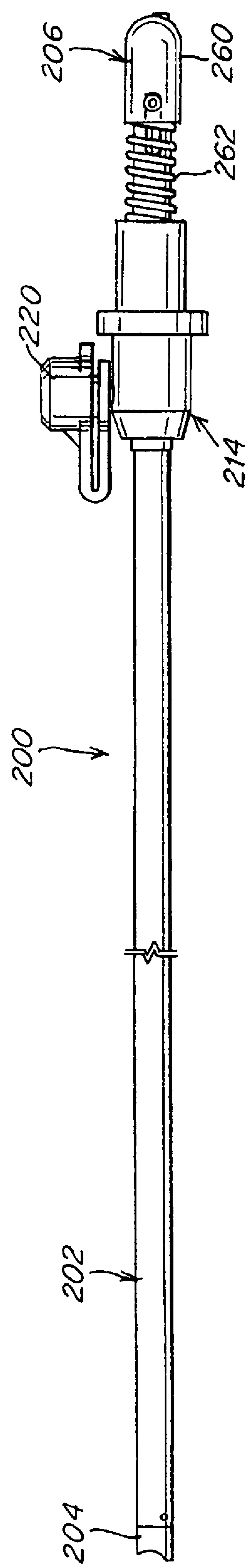

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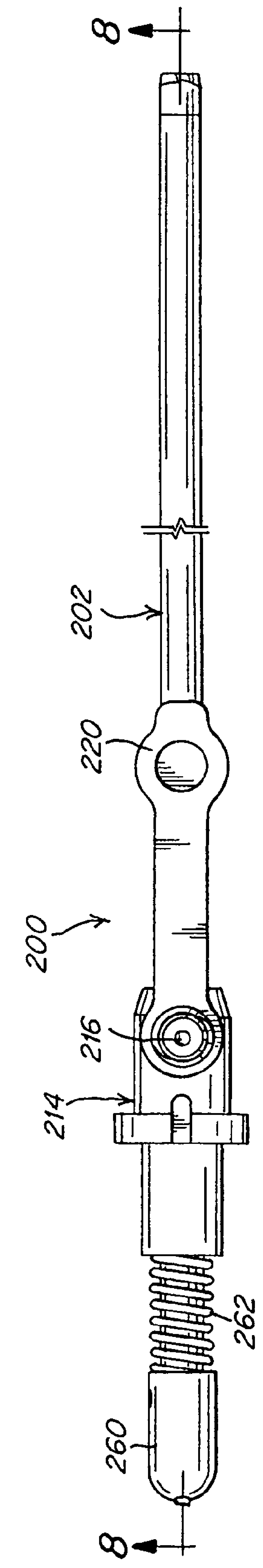

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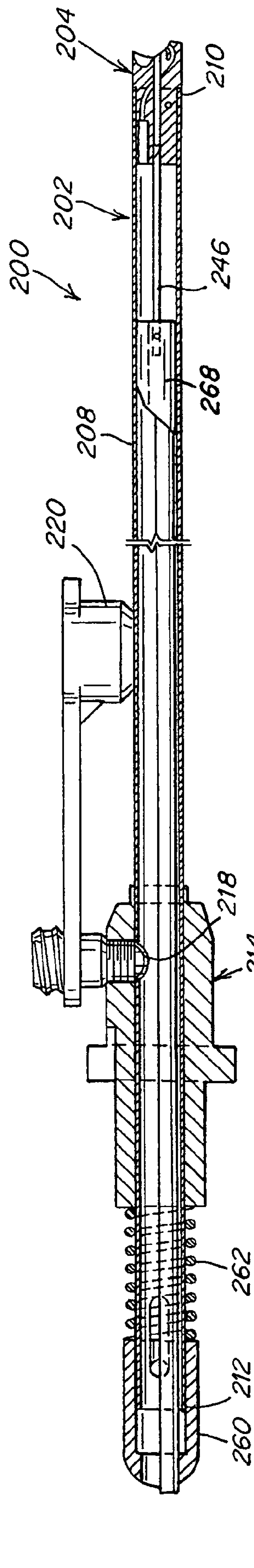

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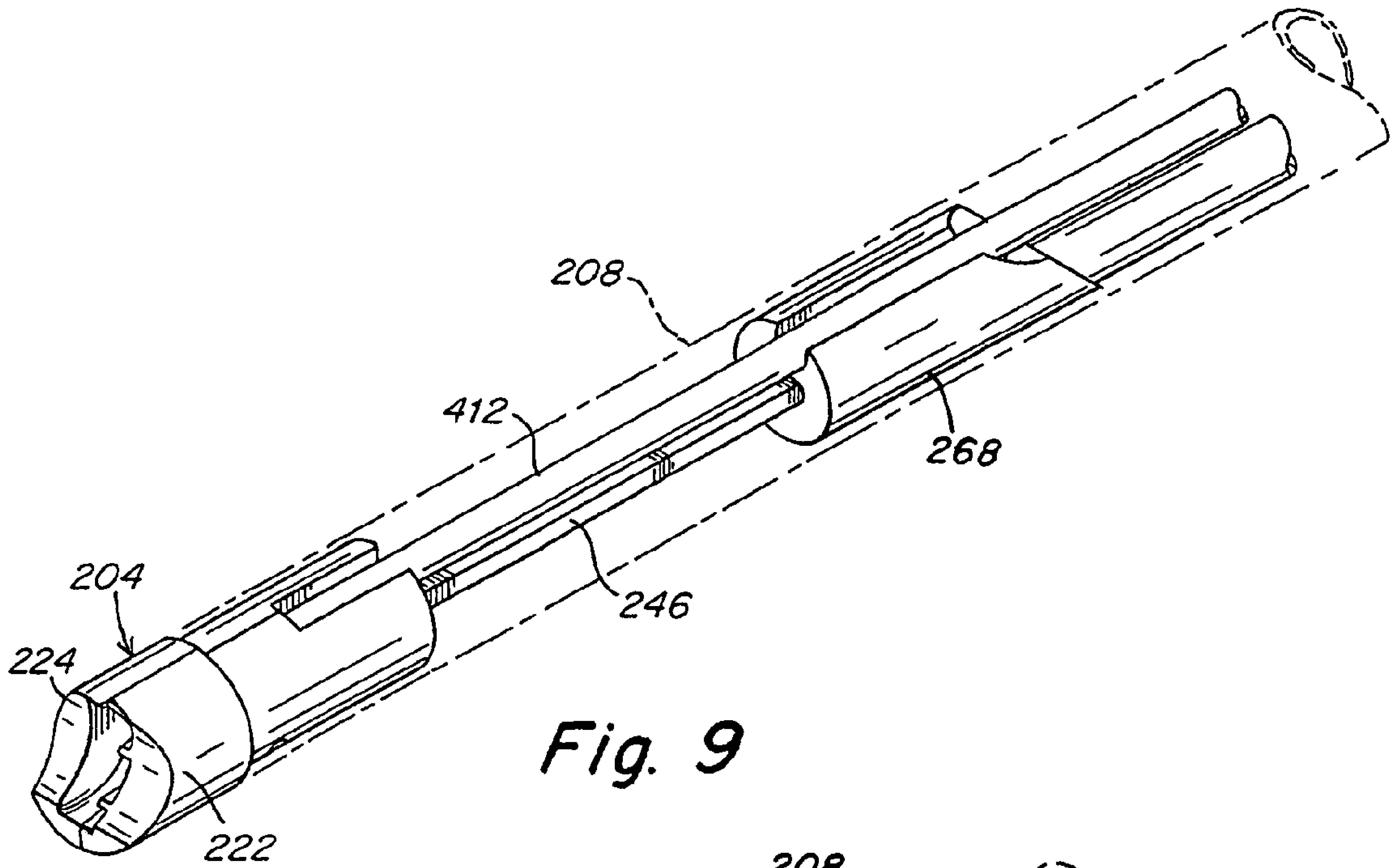

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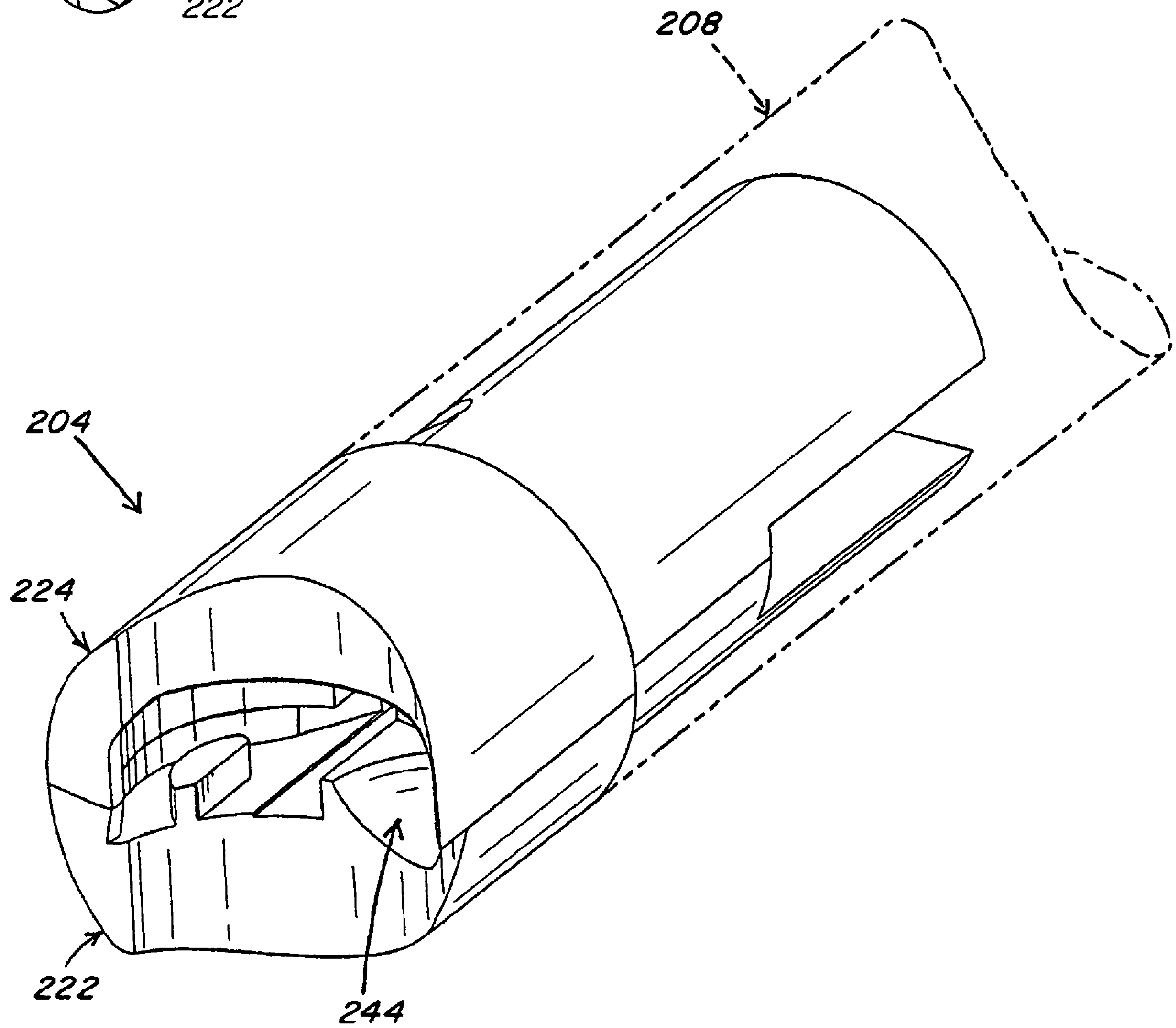

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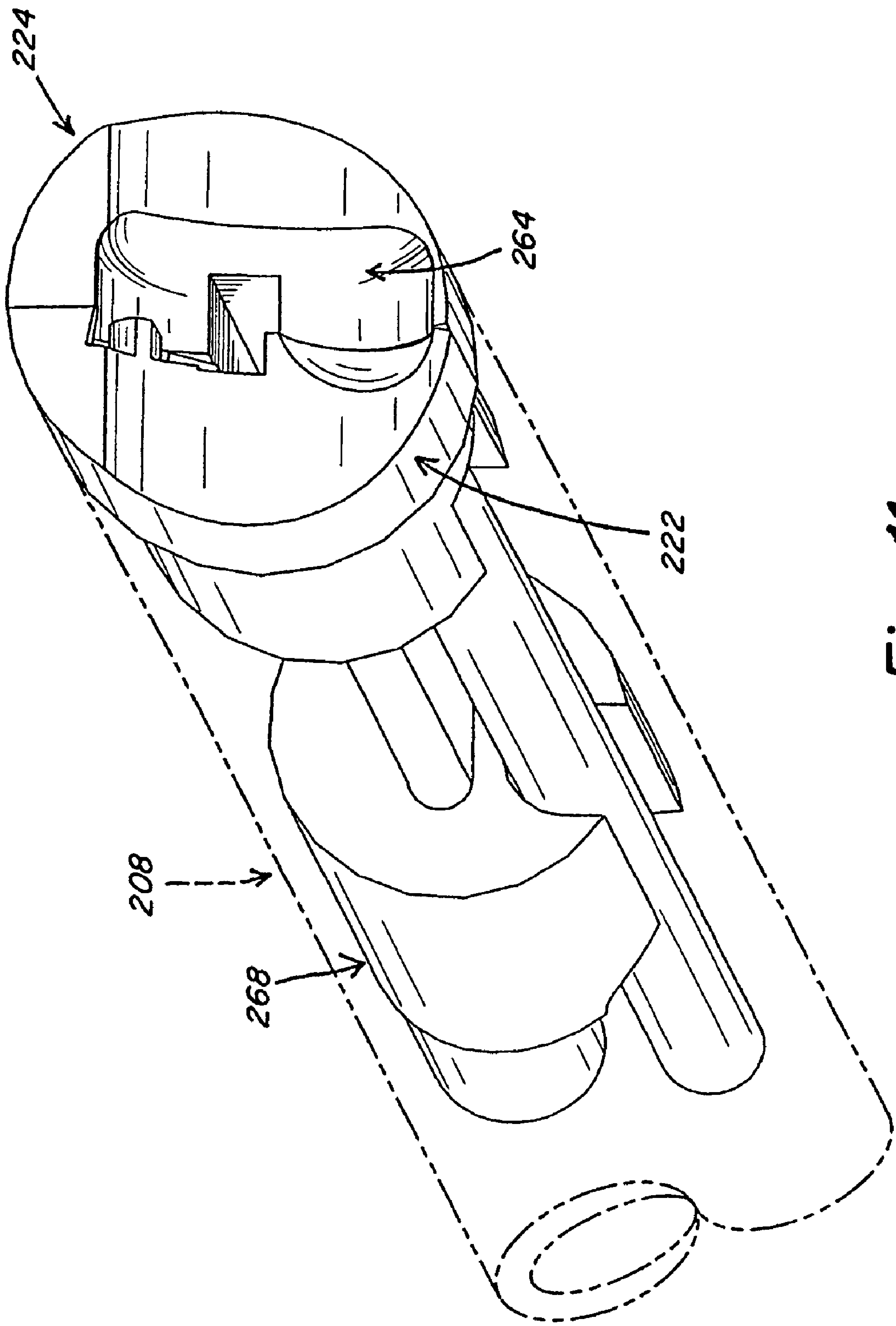

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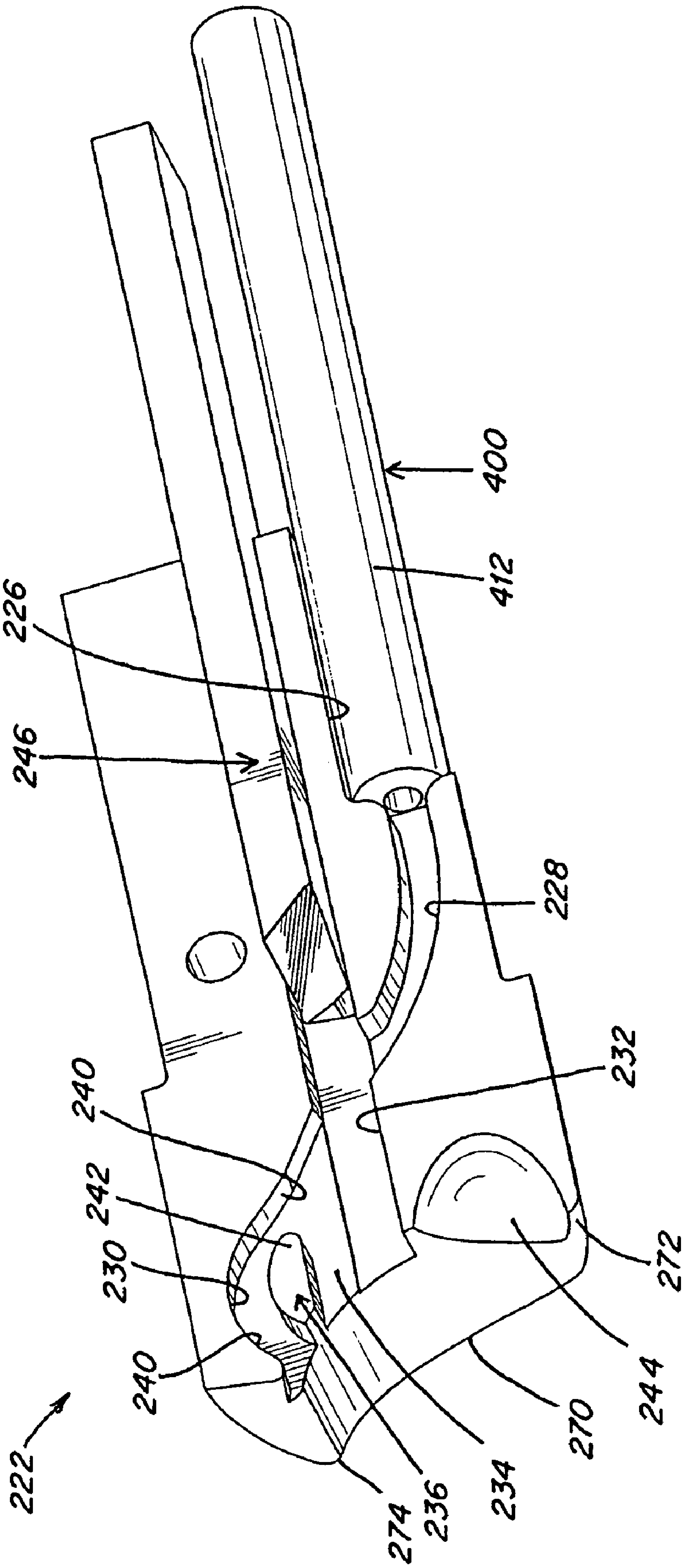
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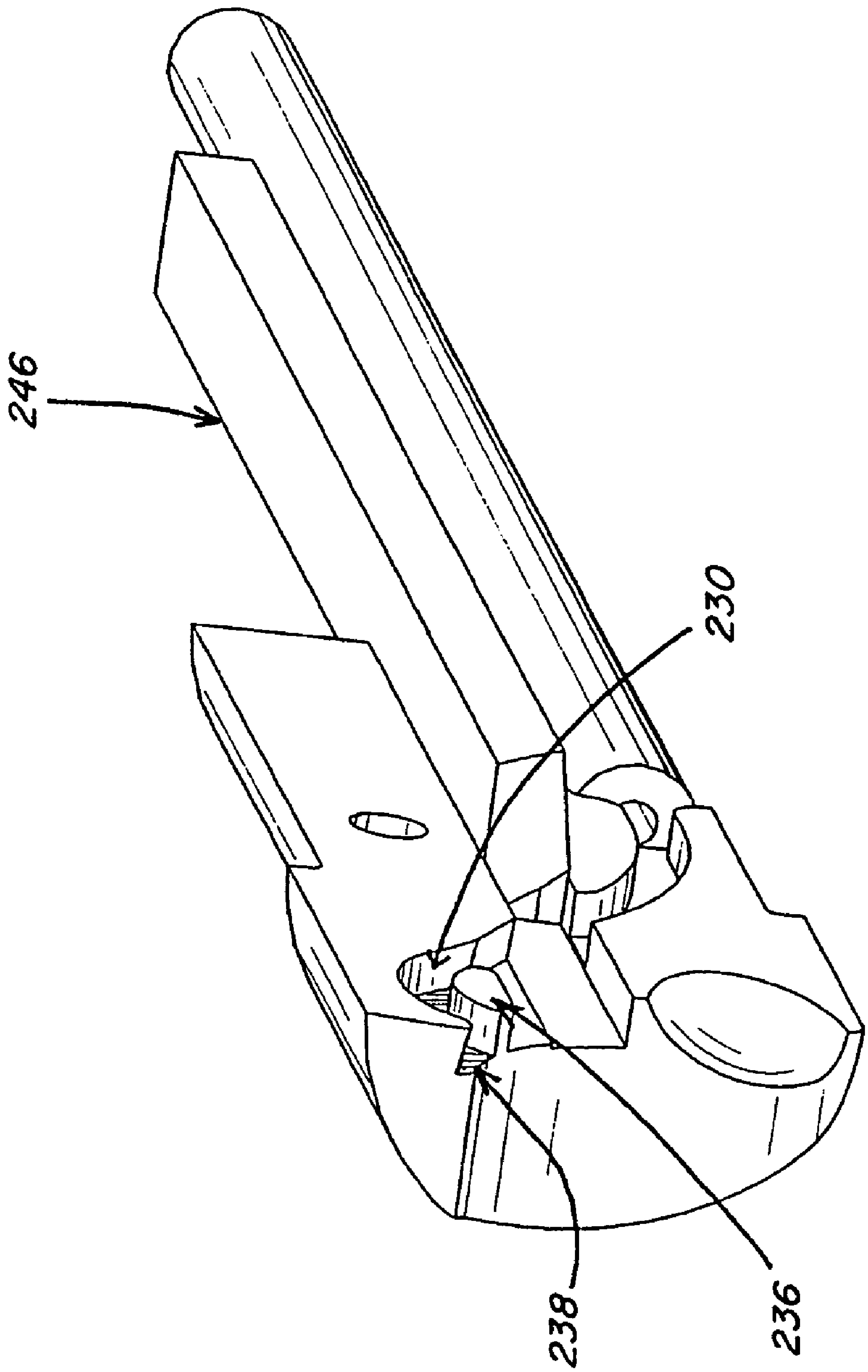

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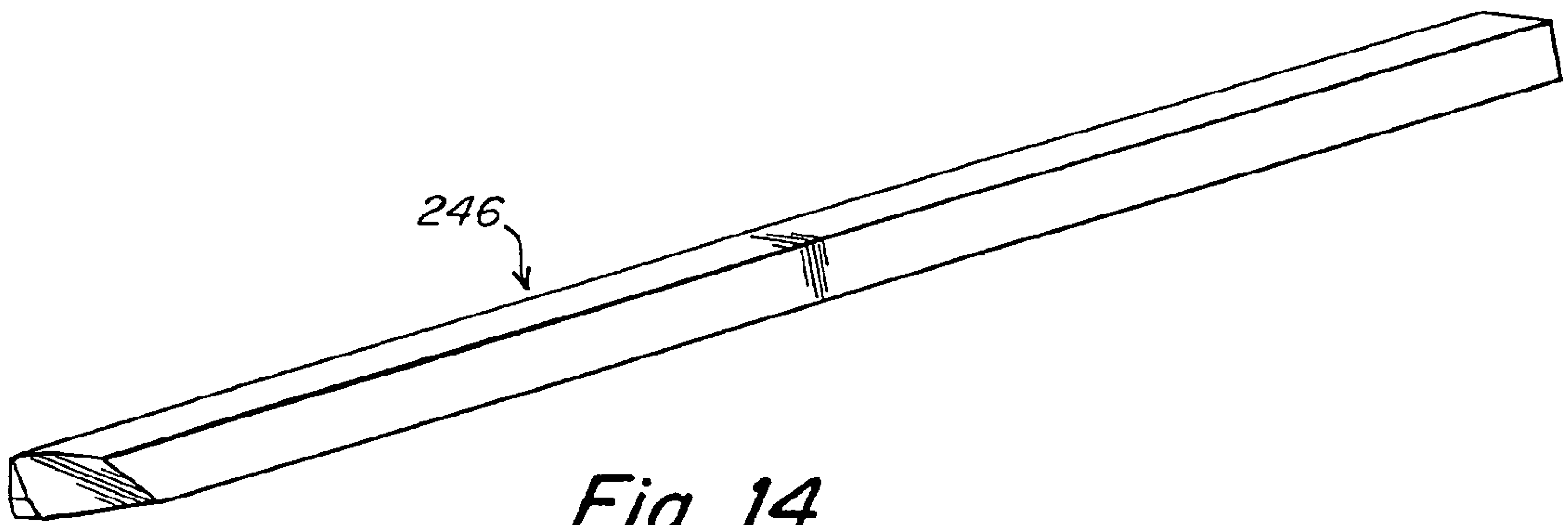

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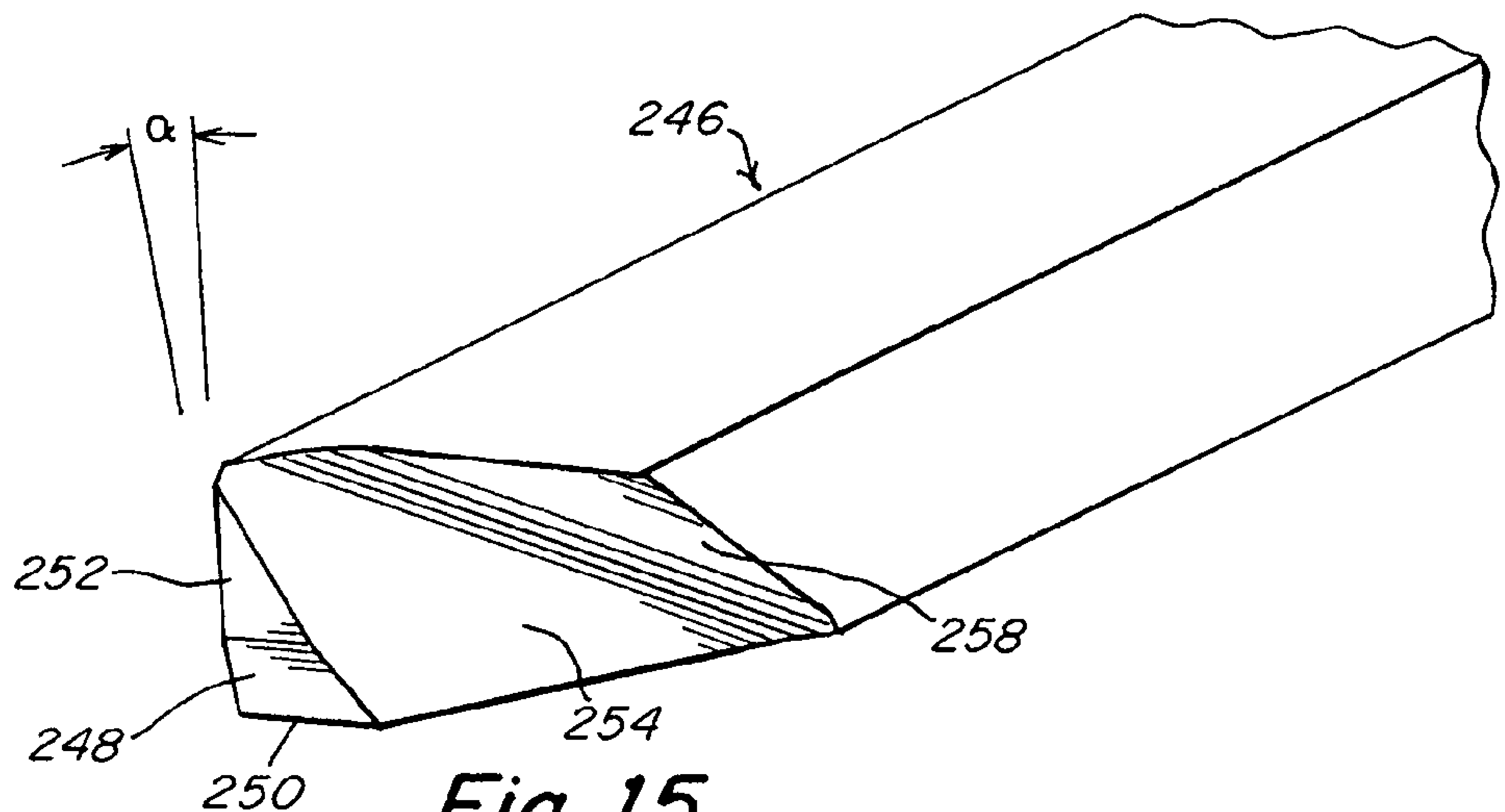

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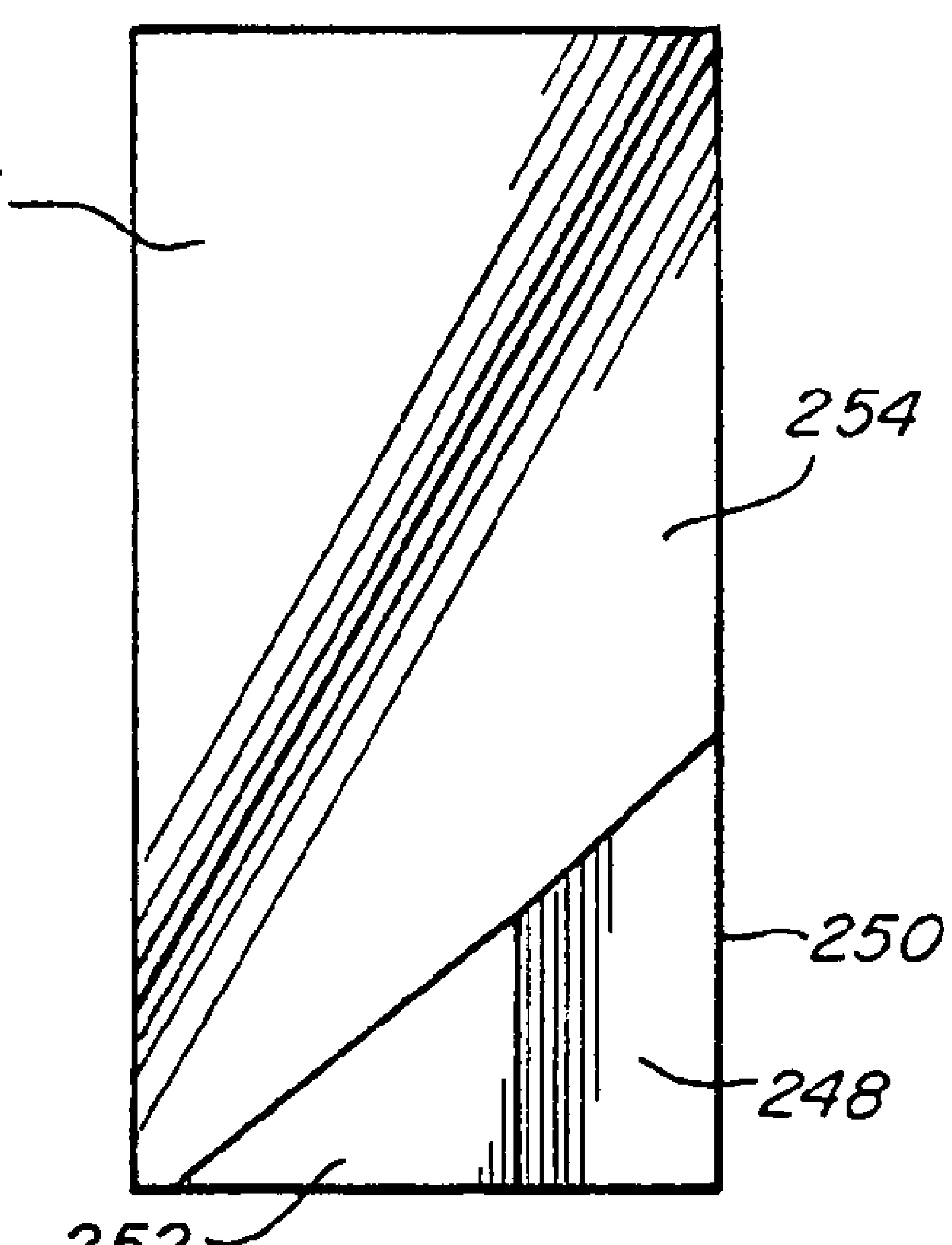

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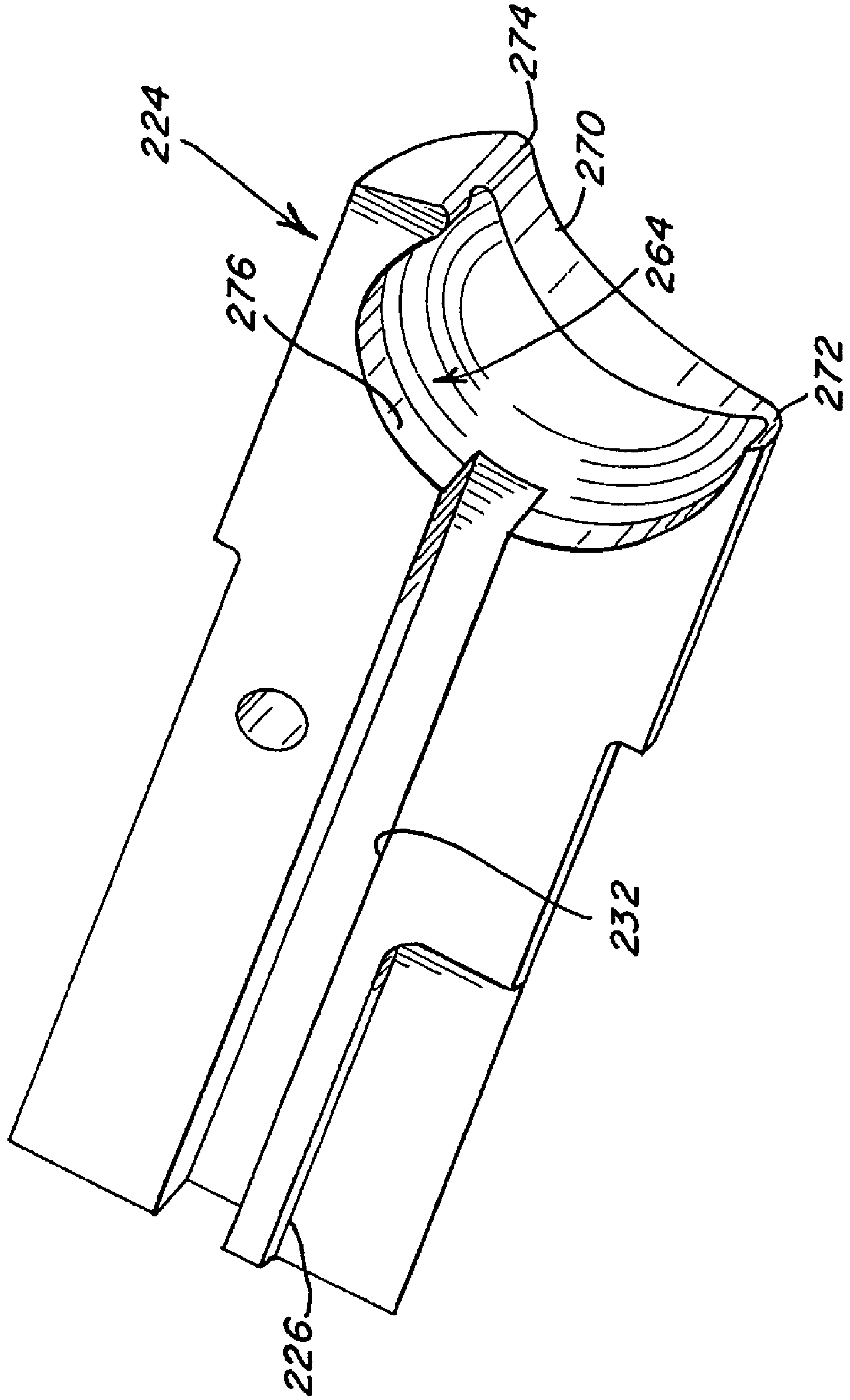

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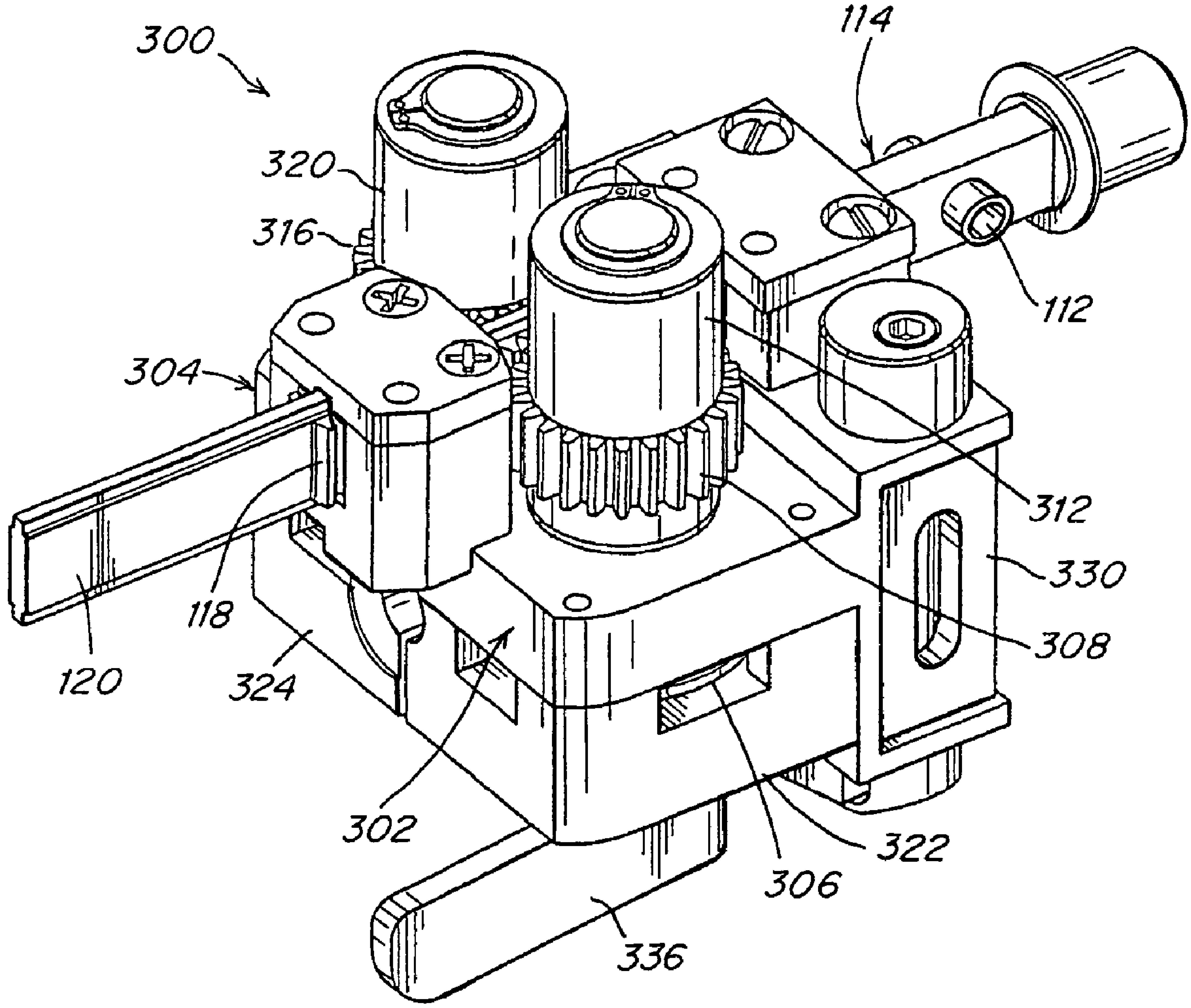

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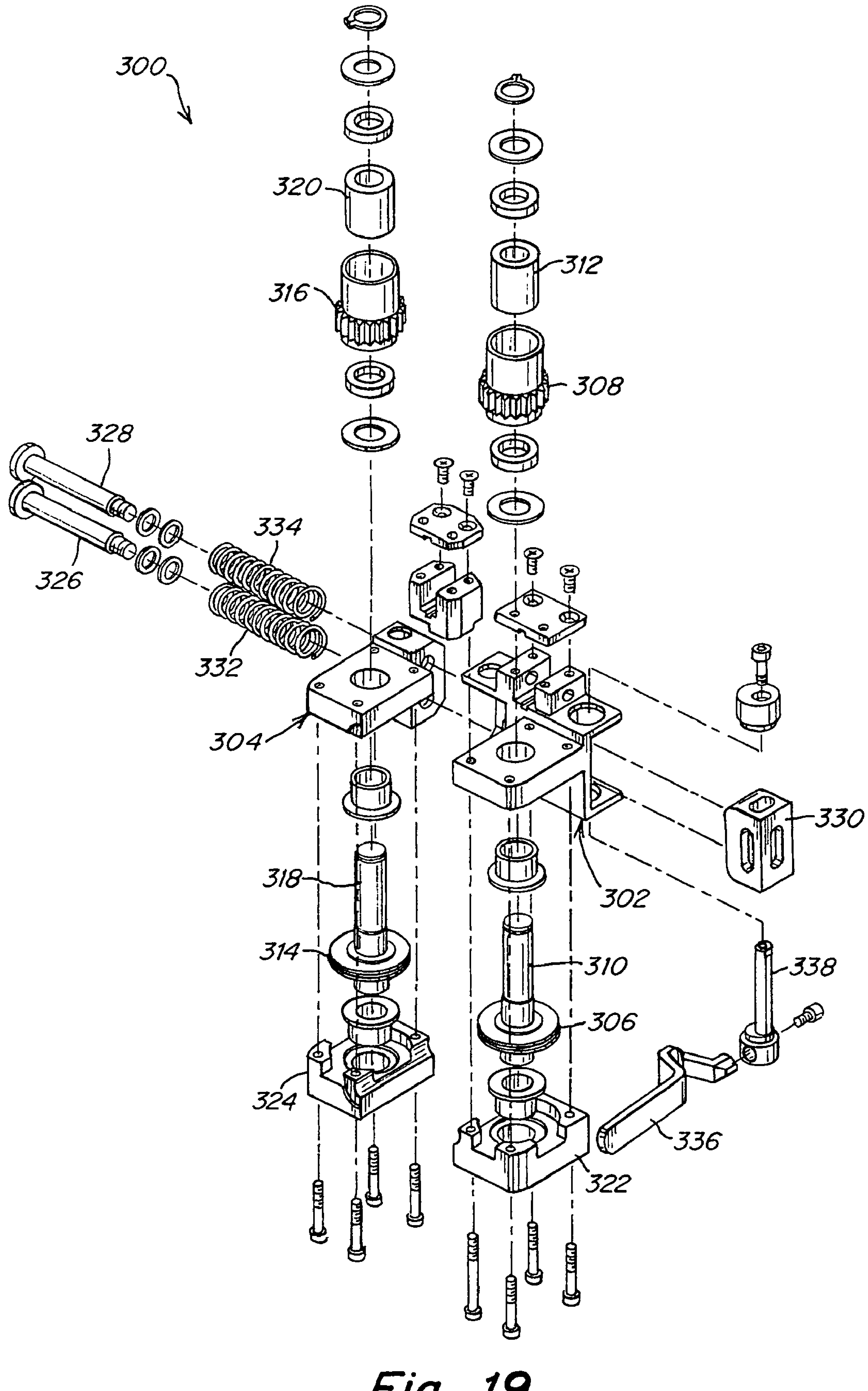
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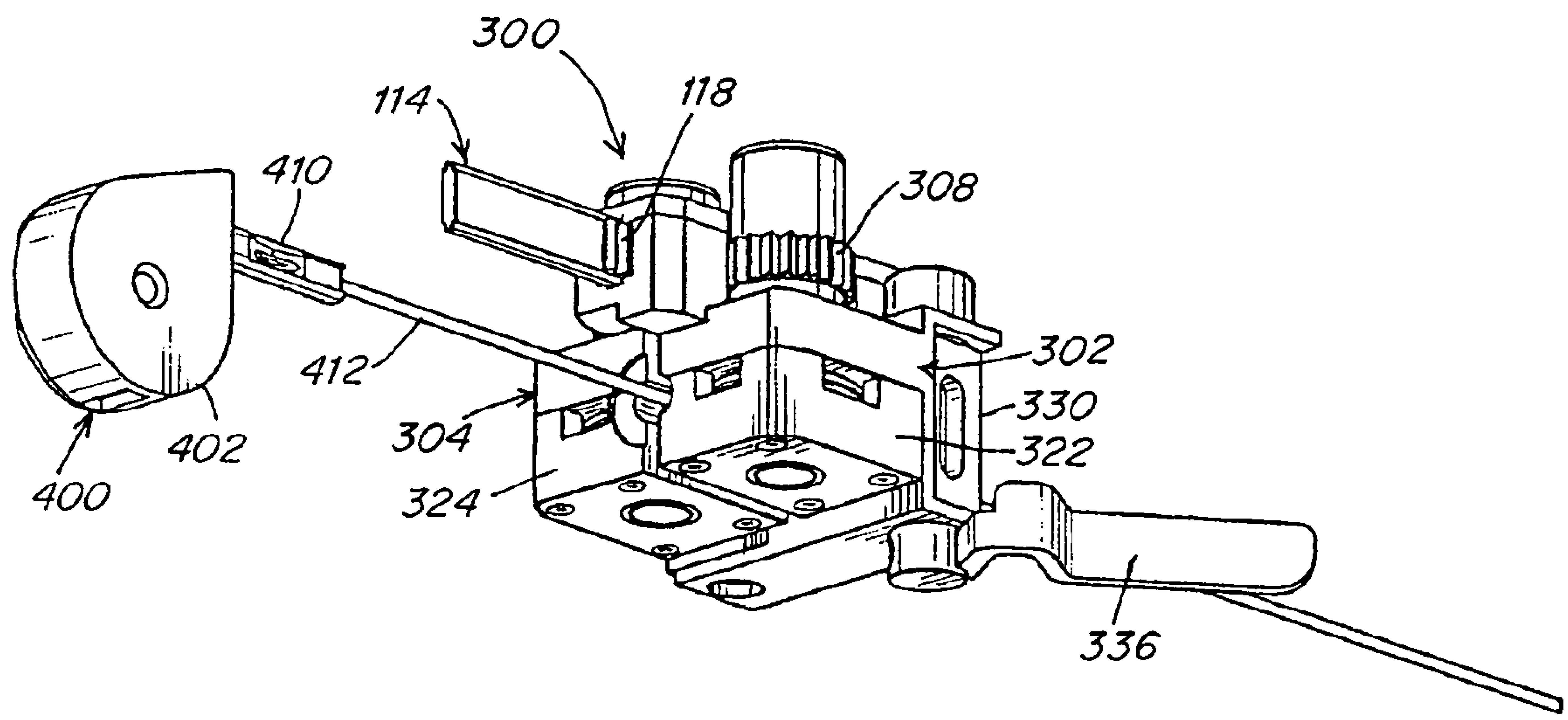
Fig. 19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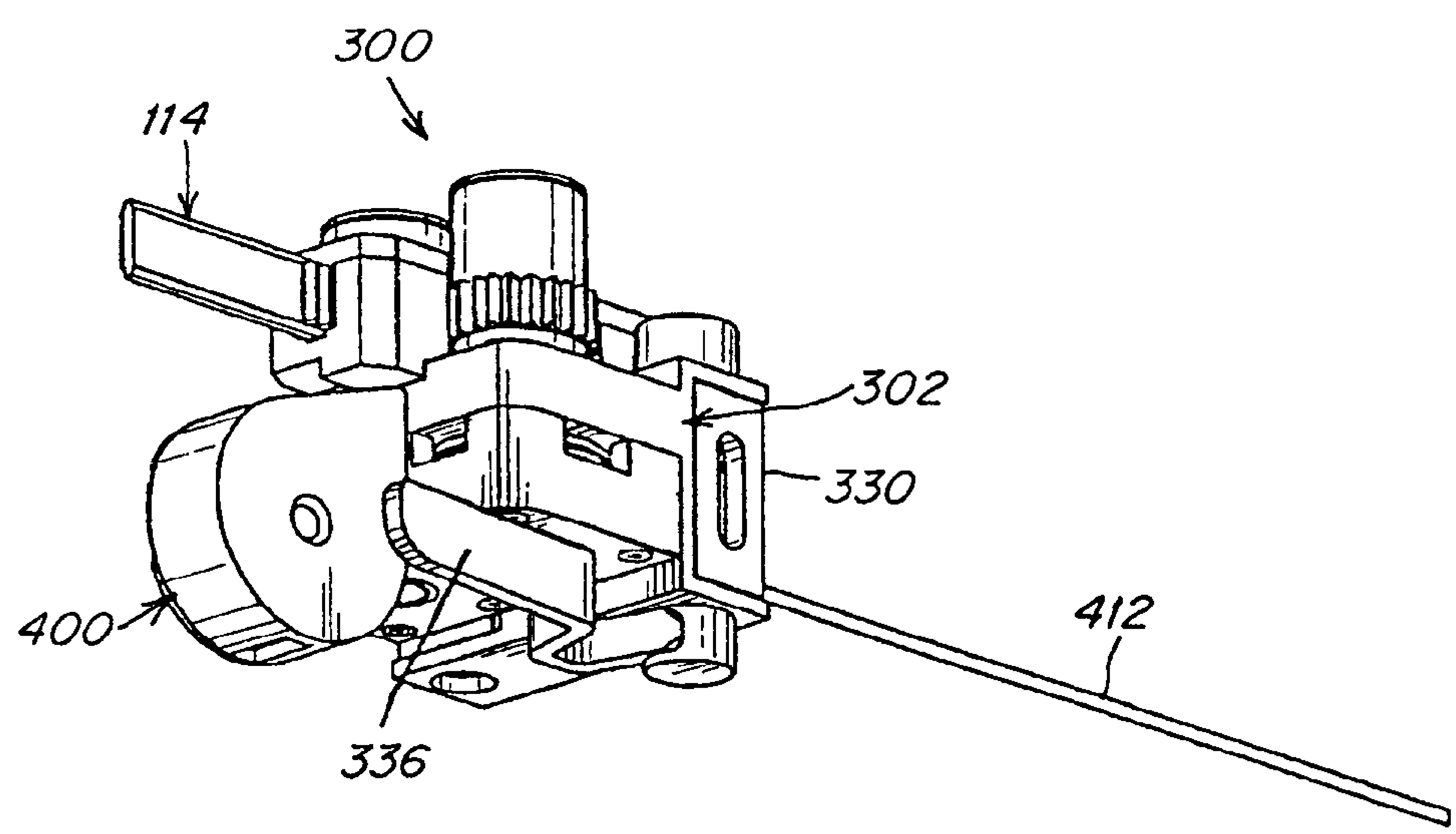
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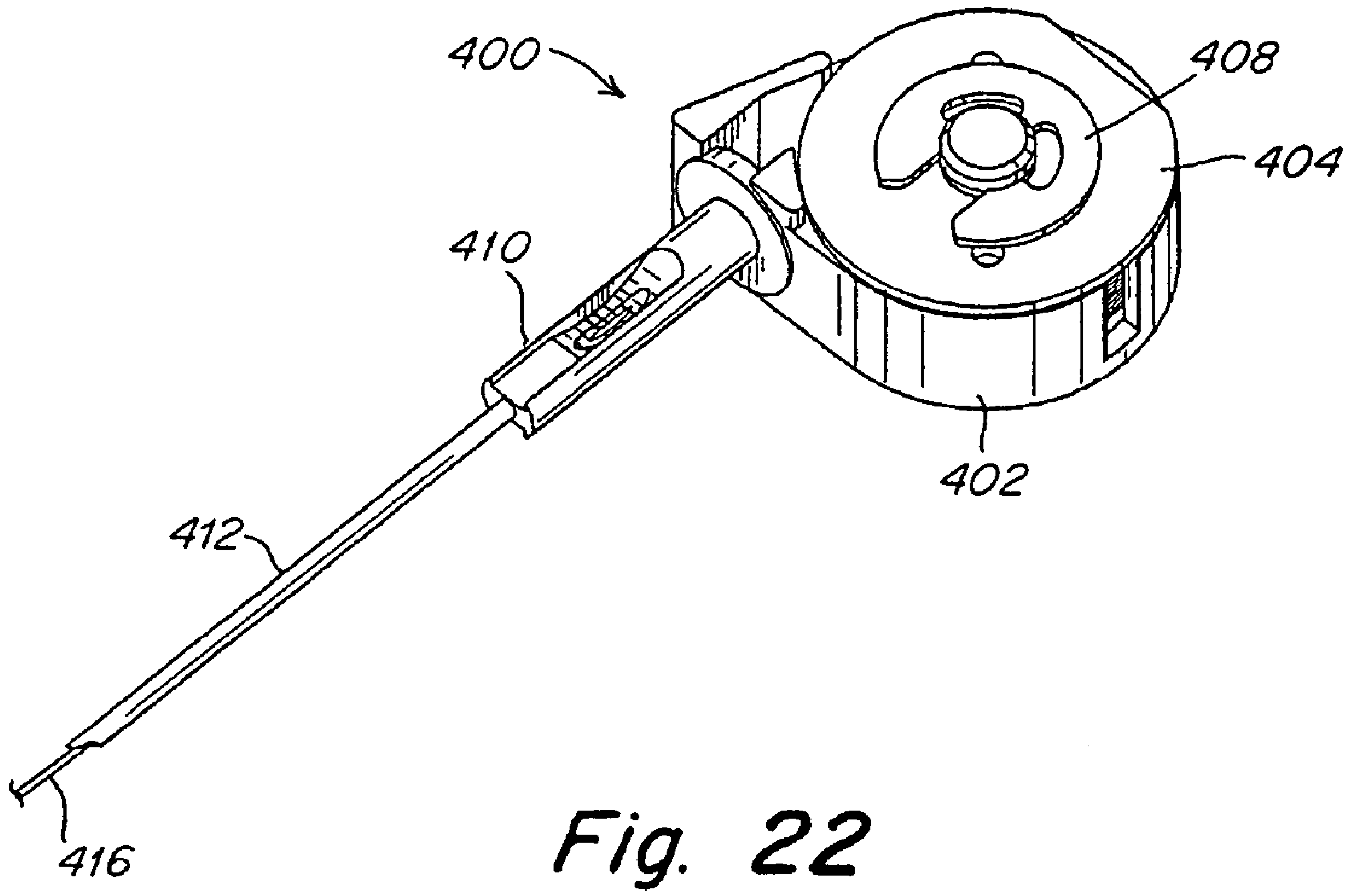

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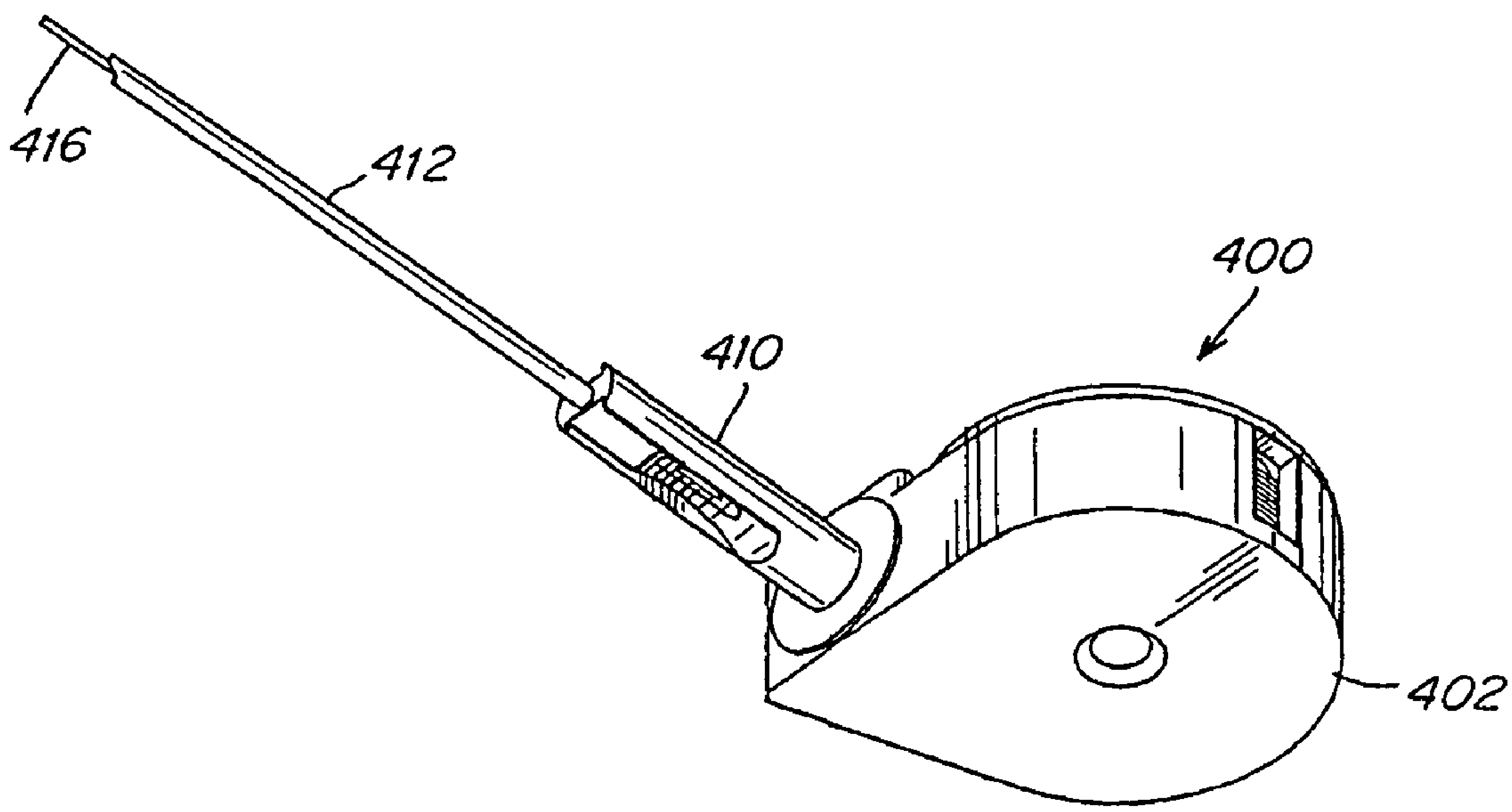

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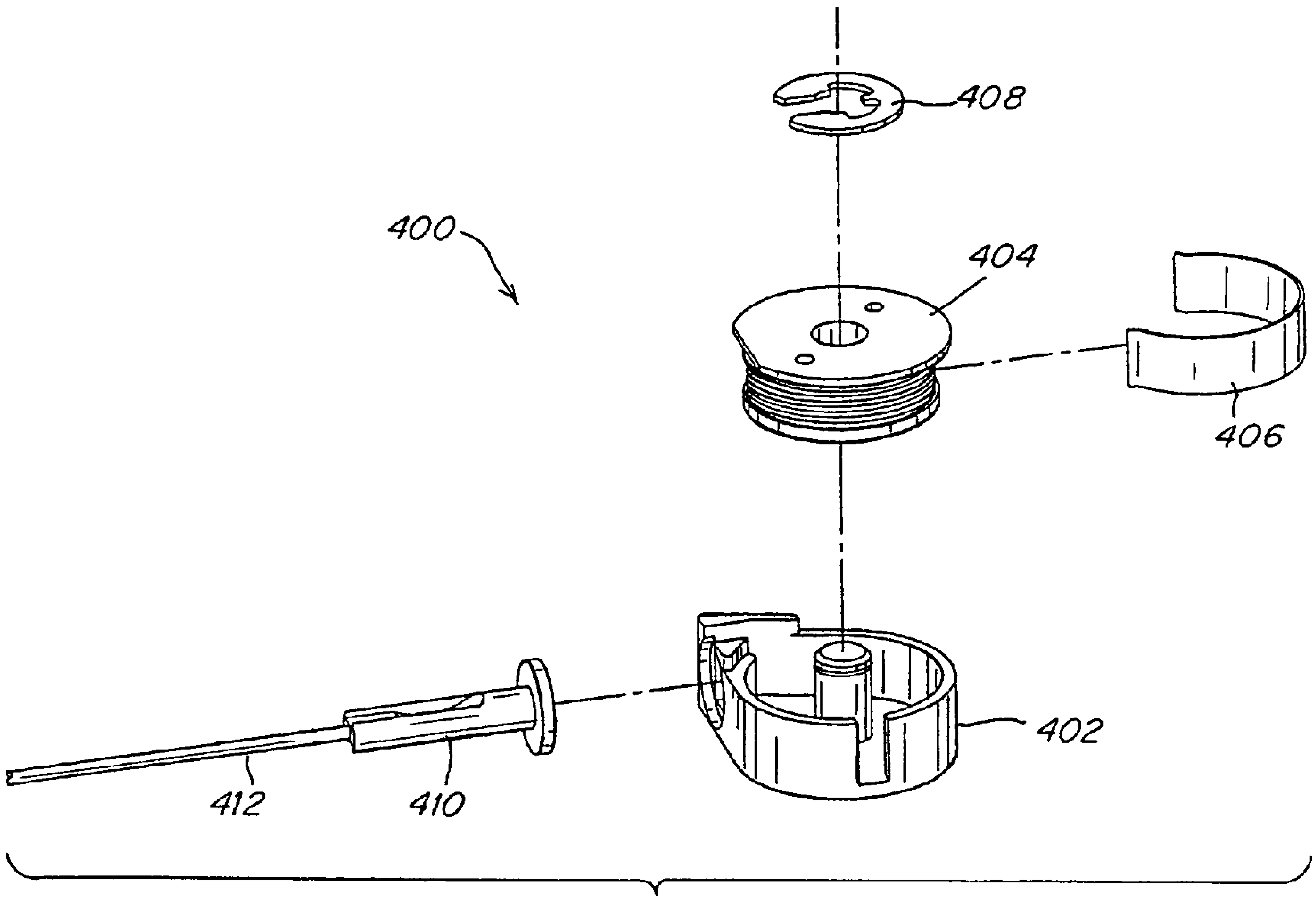

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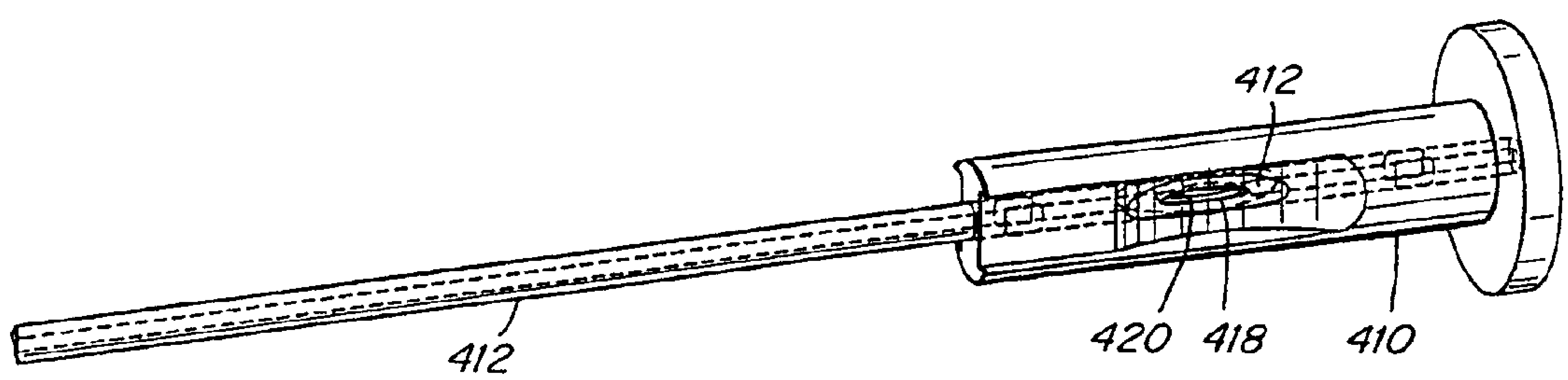

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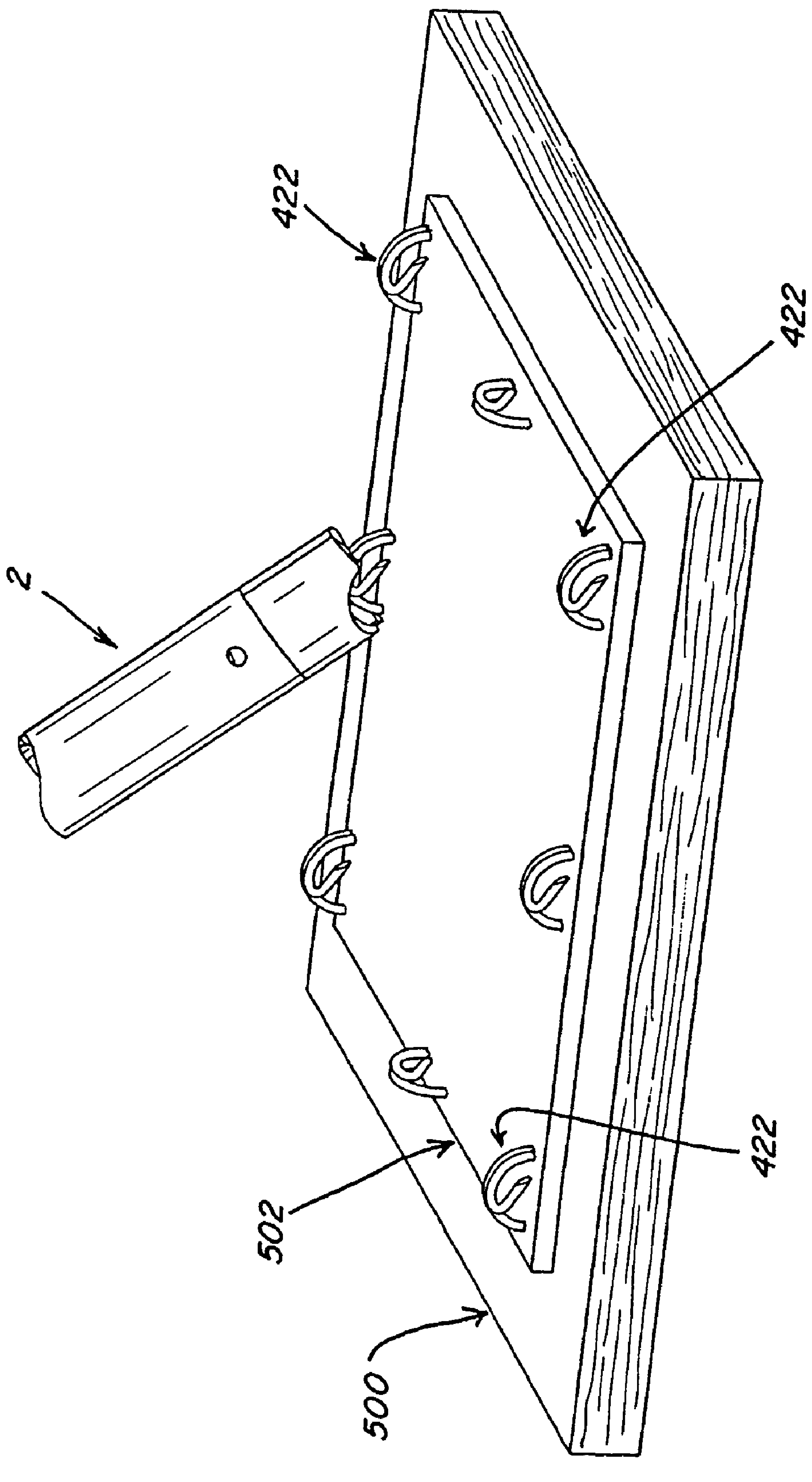

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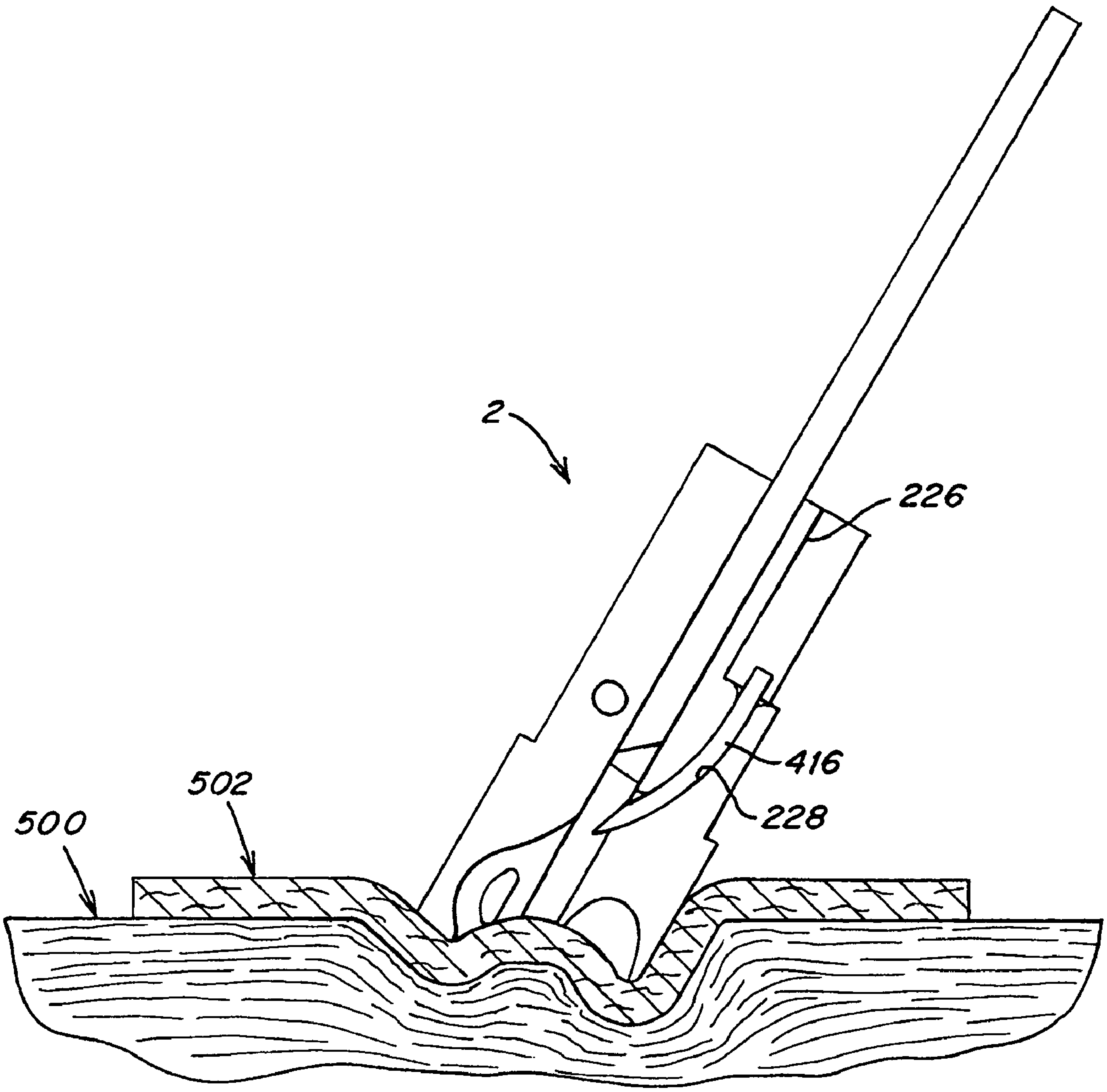

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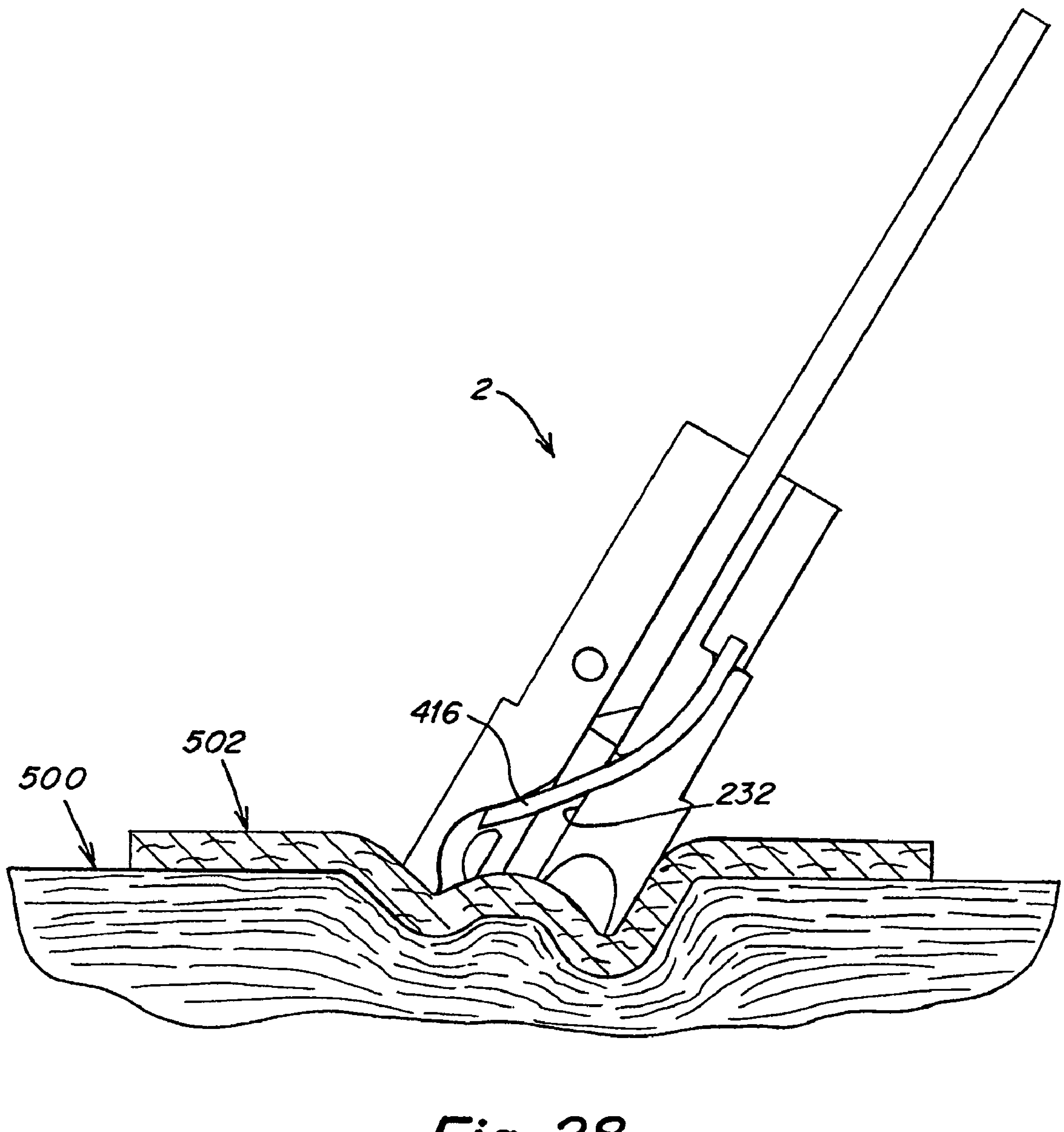

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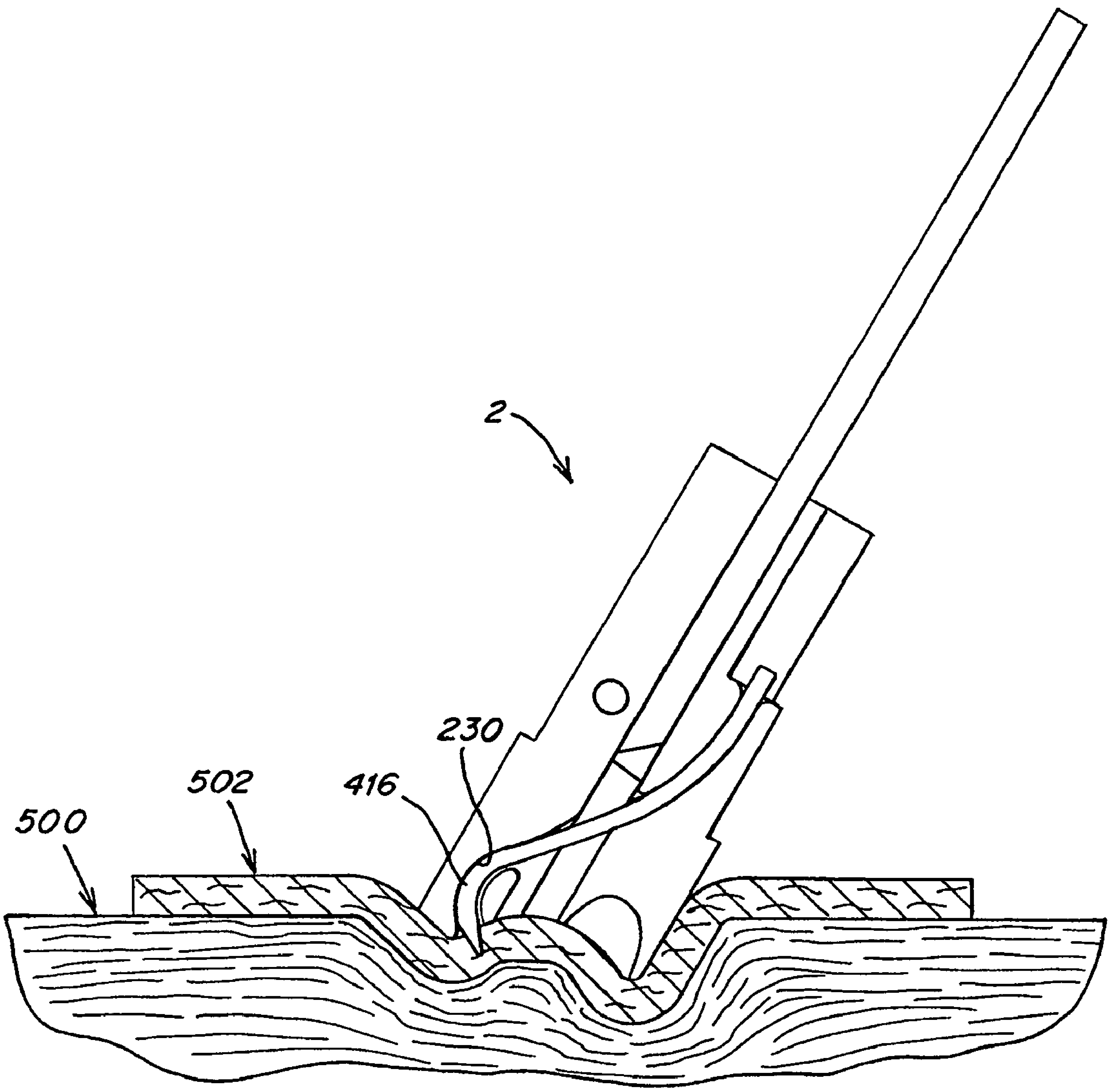

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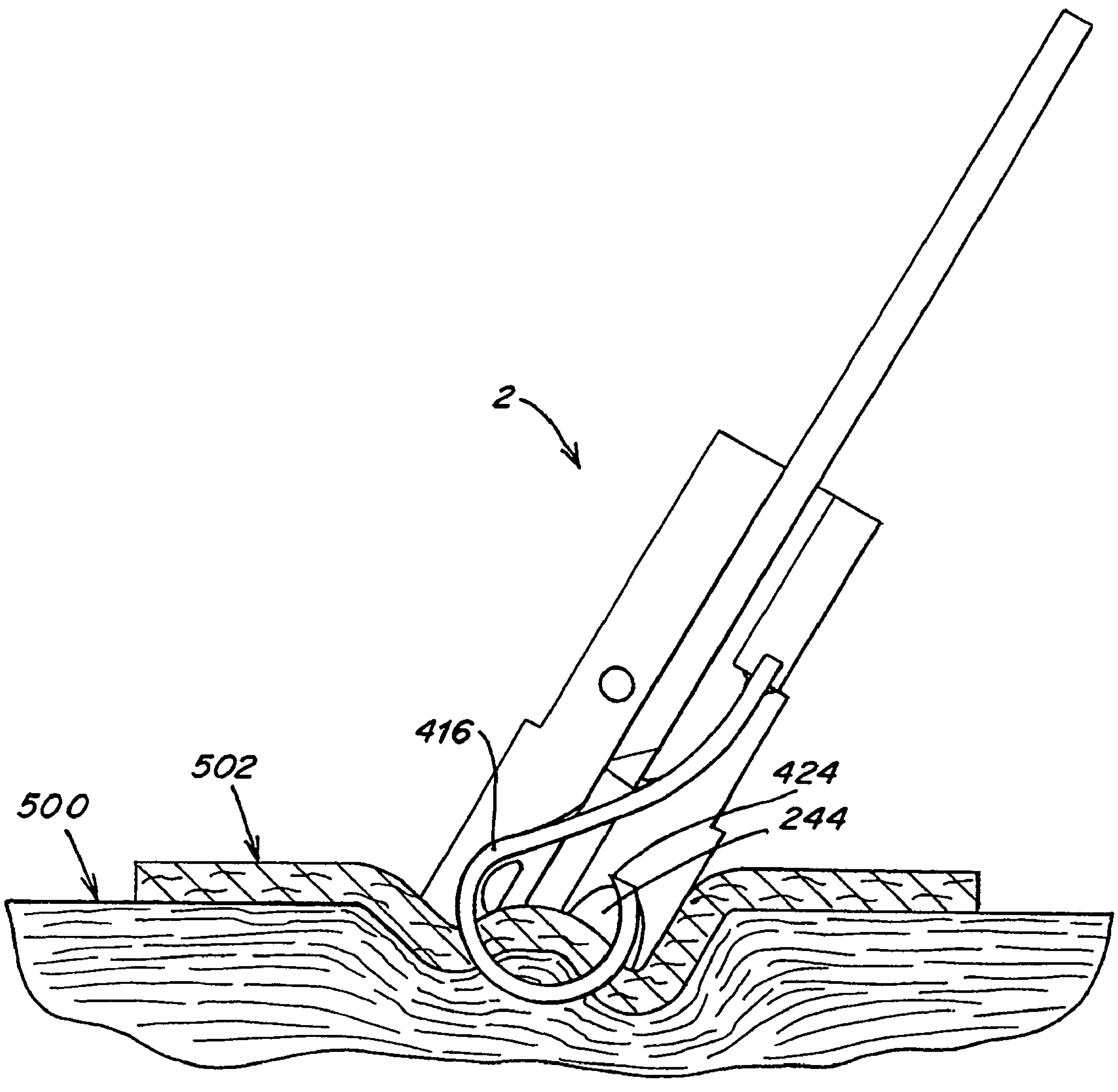

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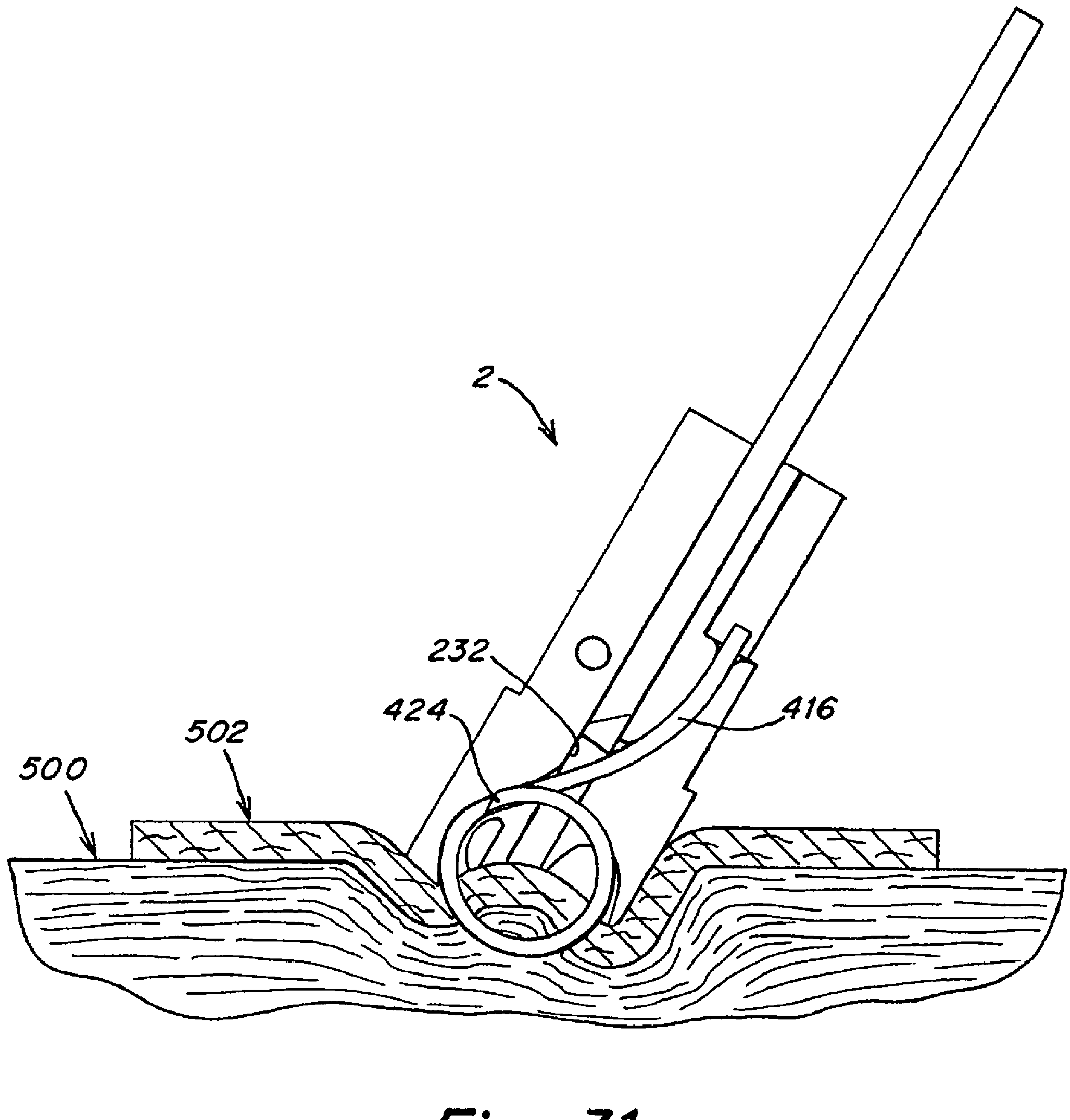

Fig. 31

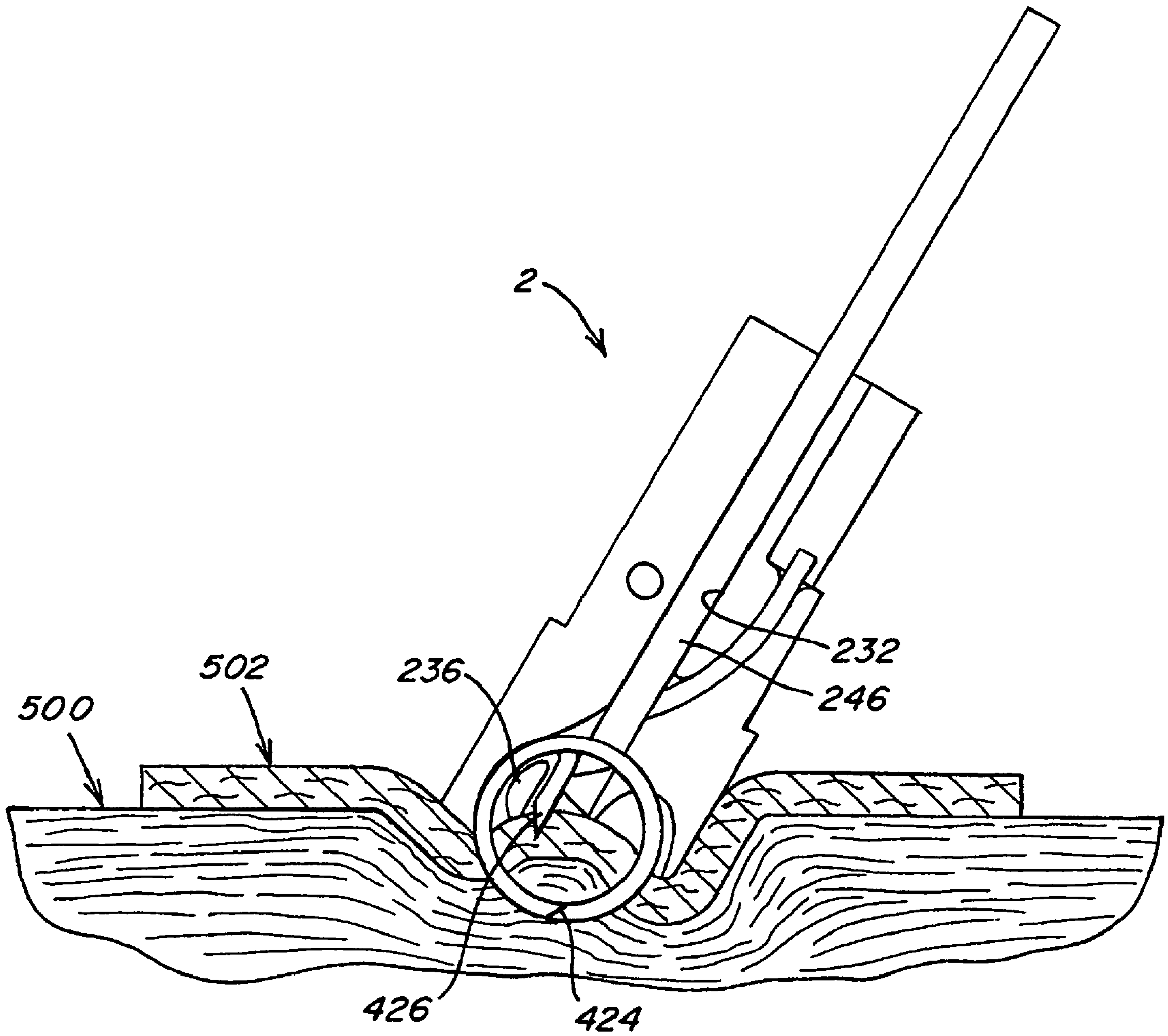

Fig. 32

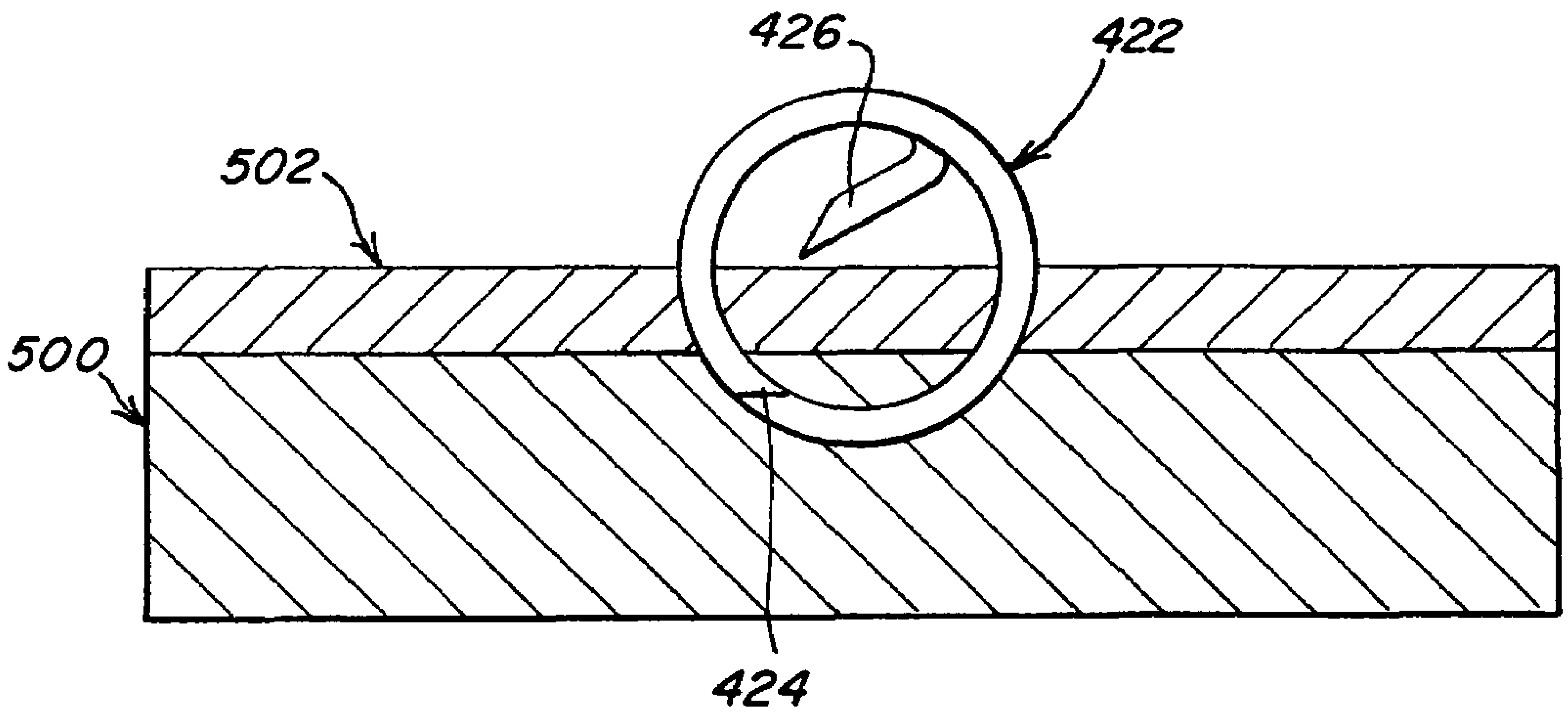

Fig. 33

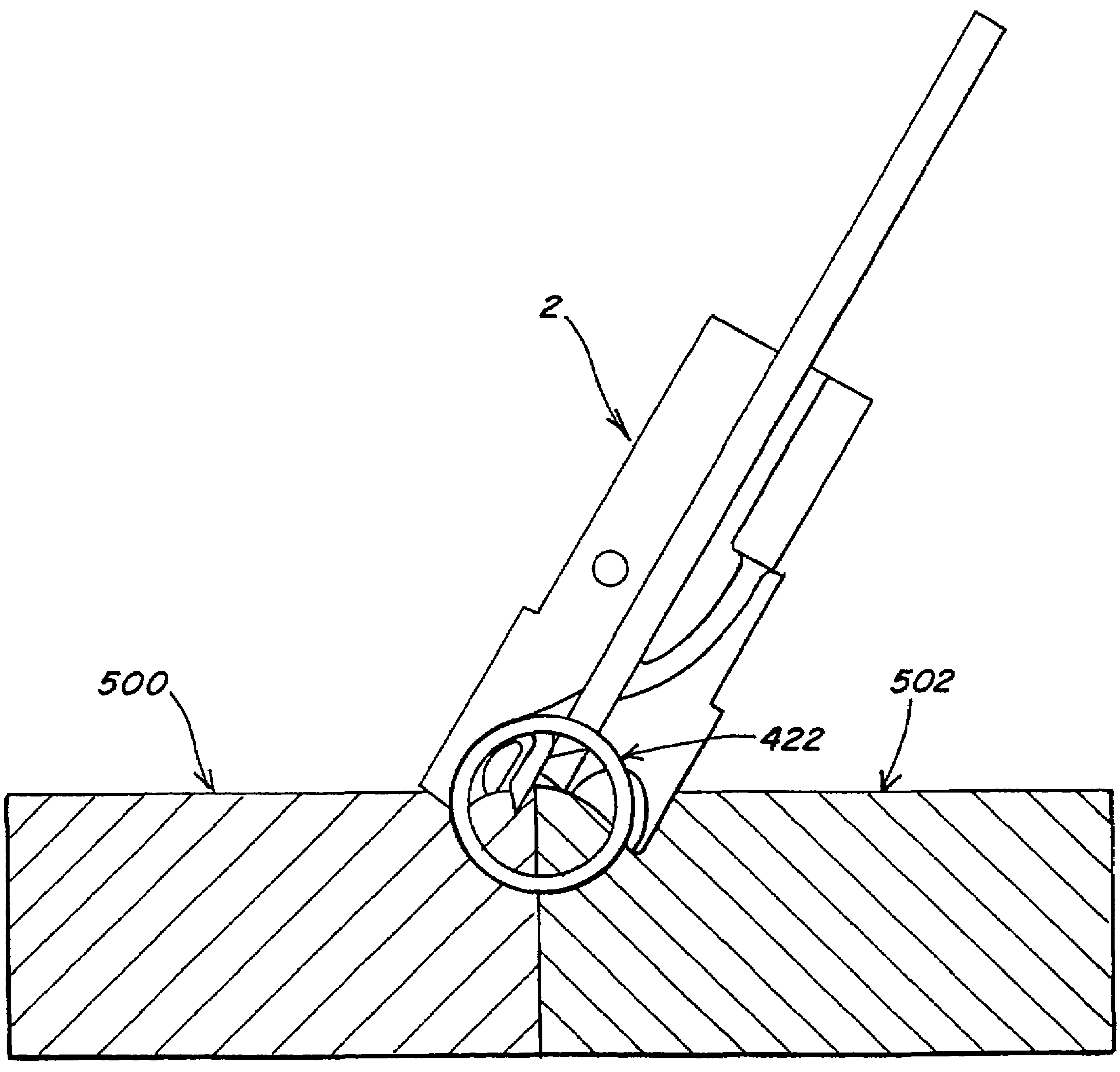

Fig. 34

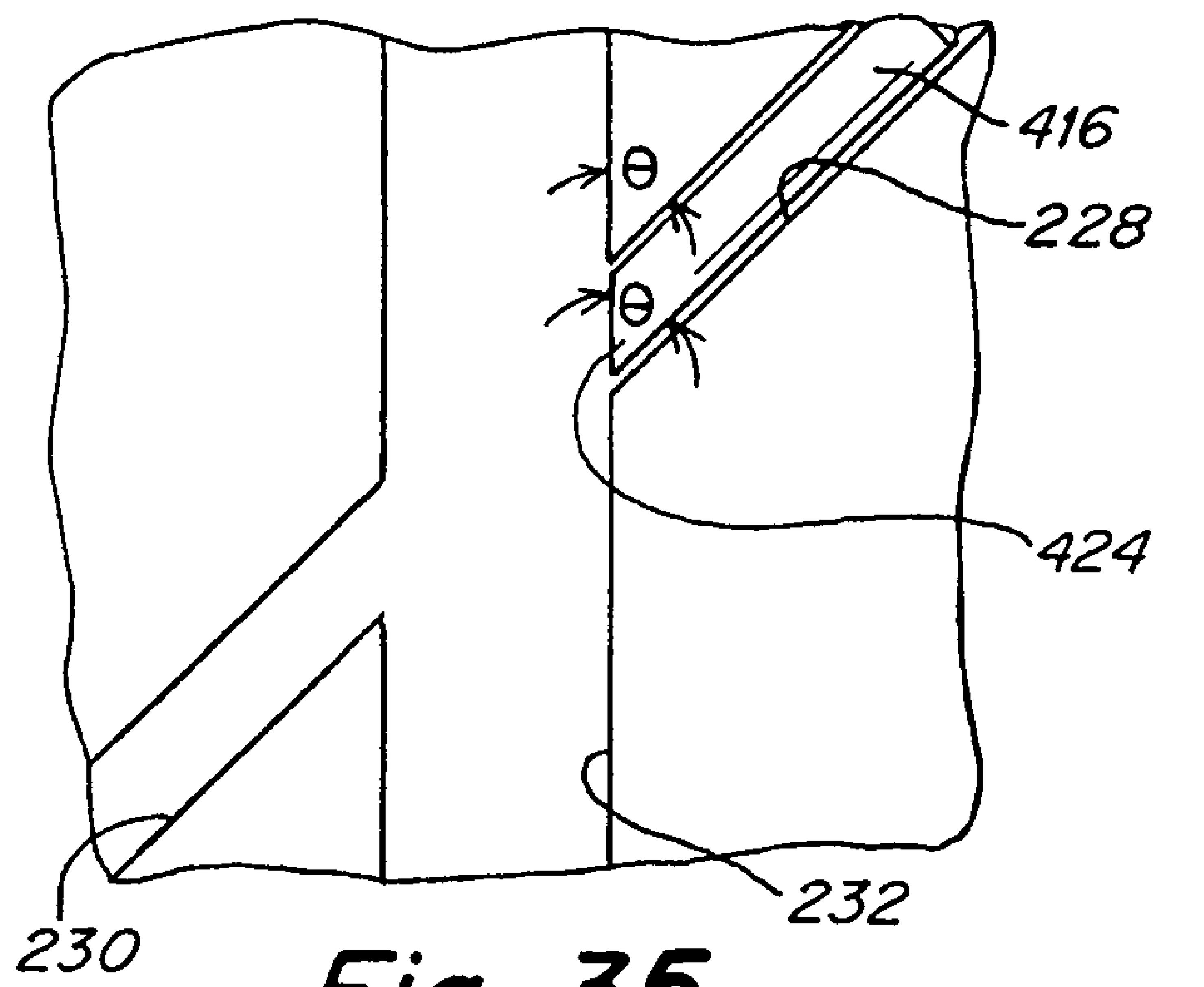

Fig. 35

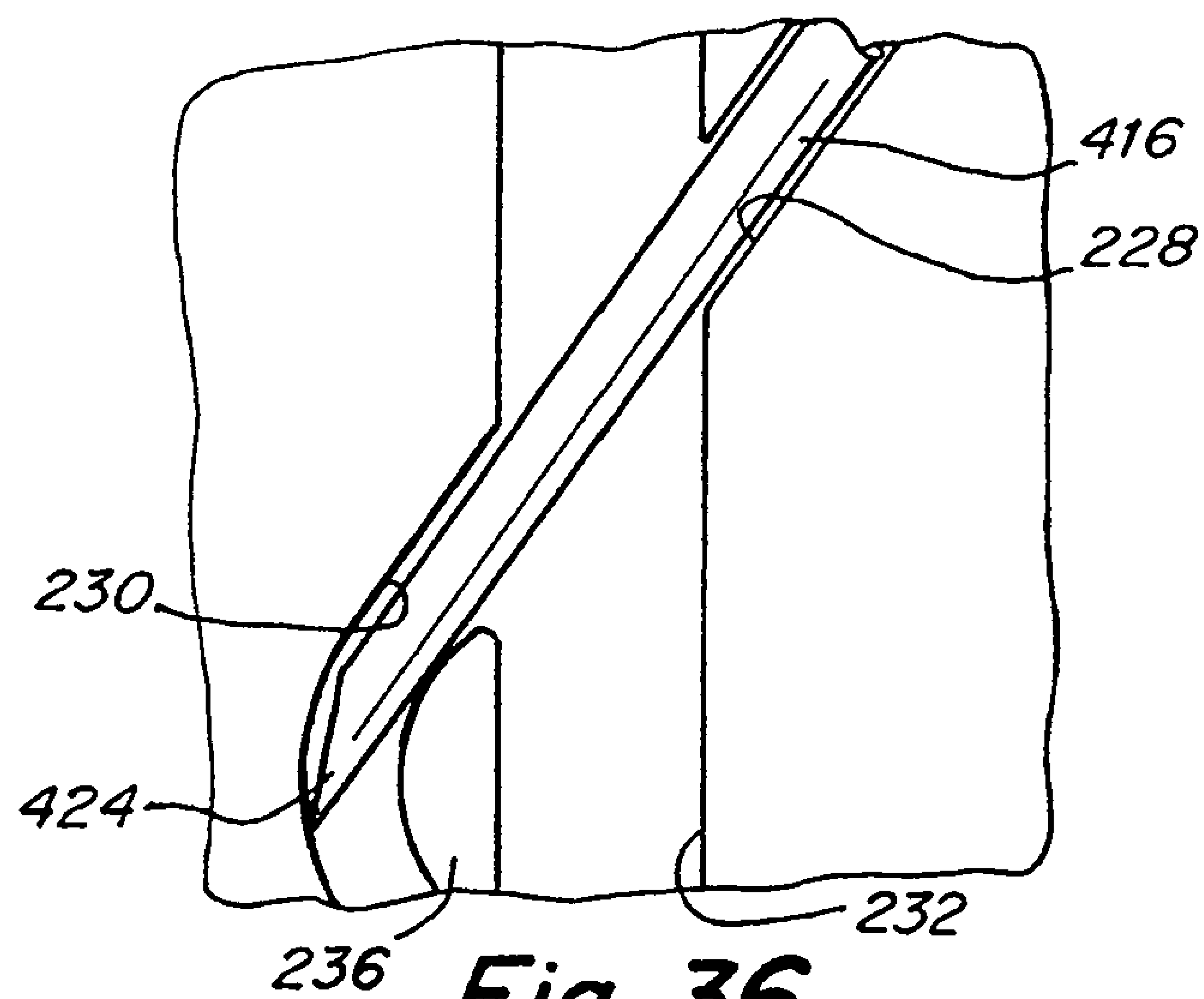

Fig. 36

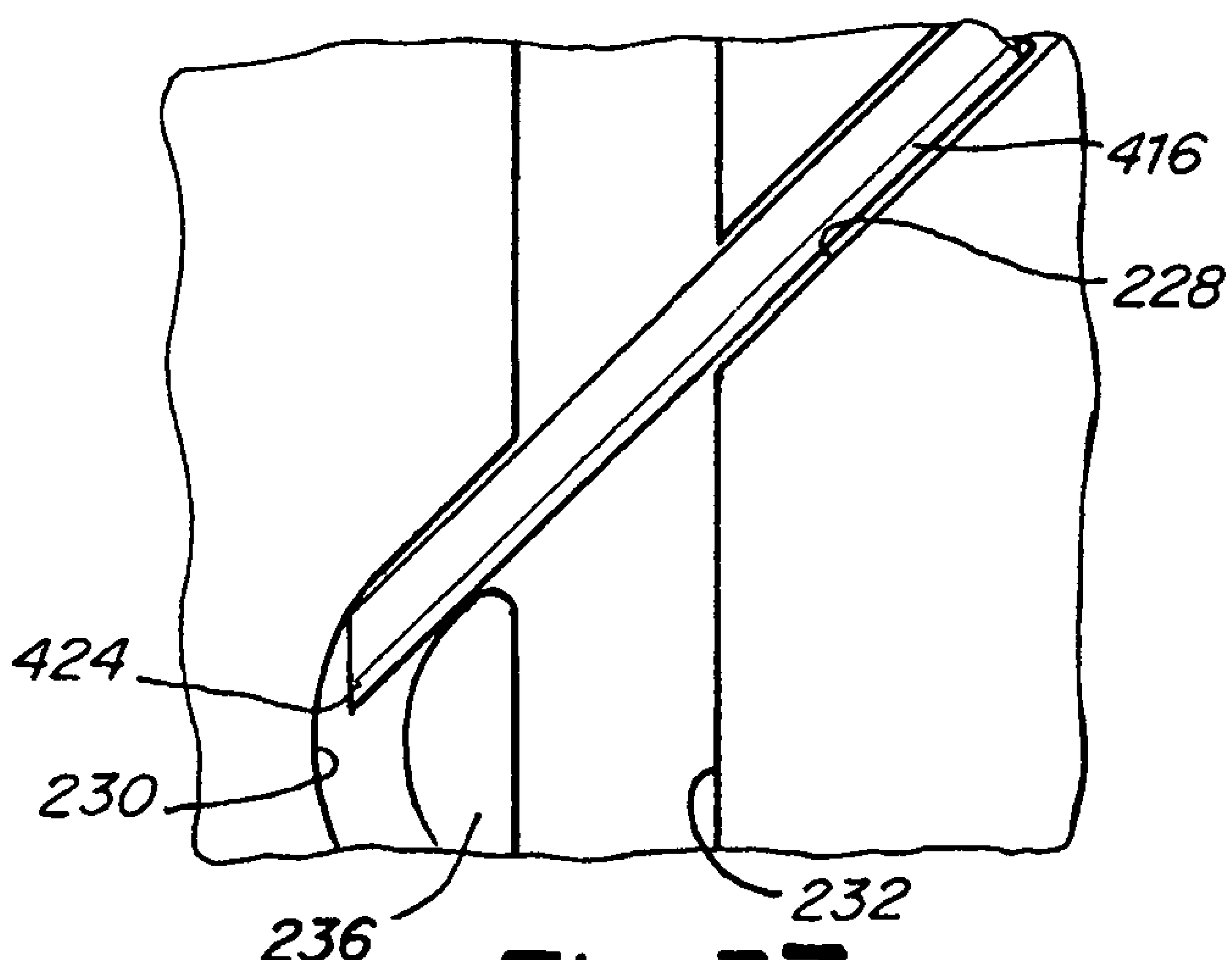

Fig. 37

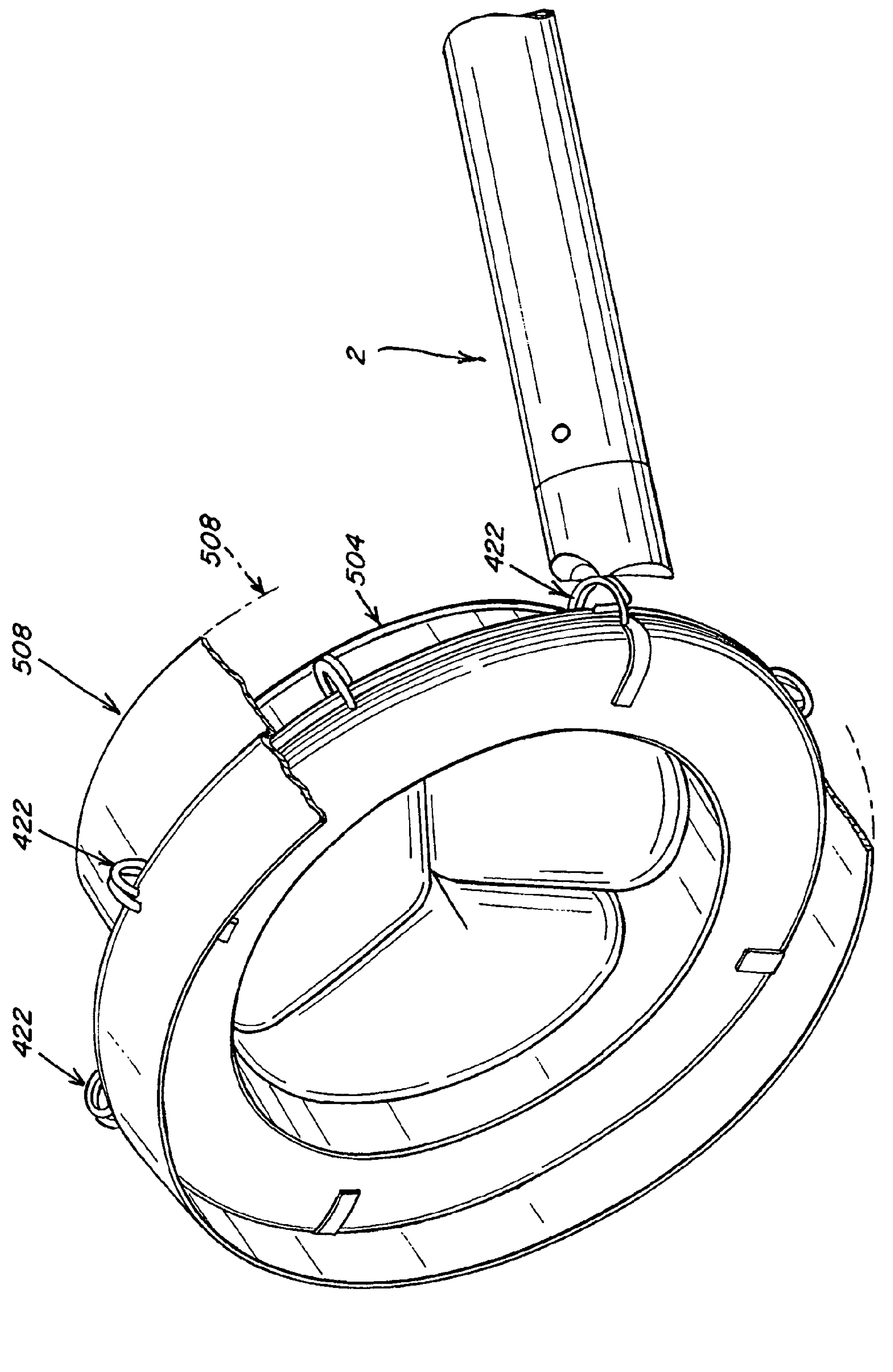

Fig. 38

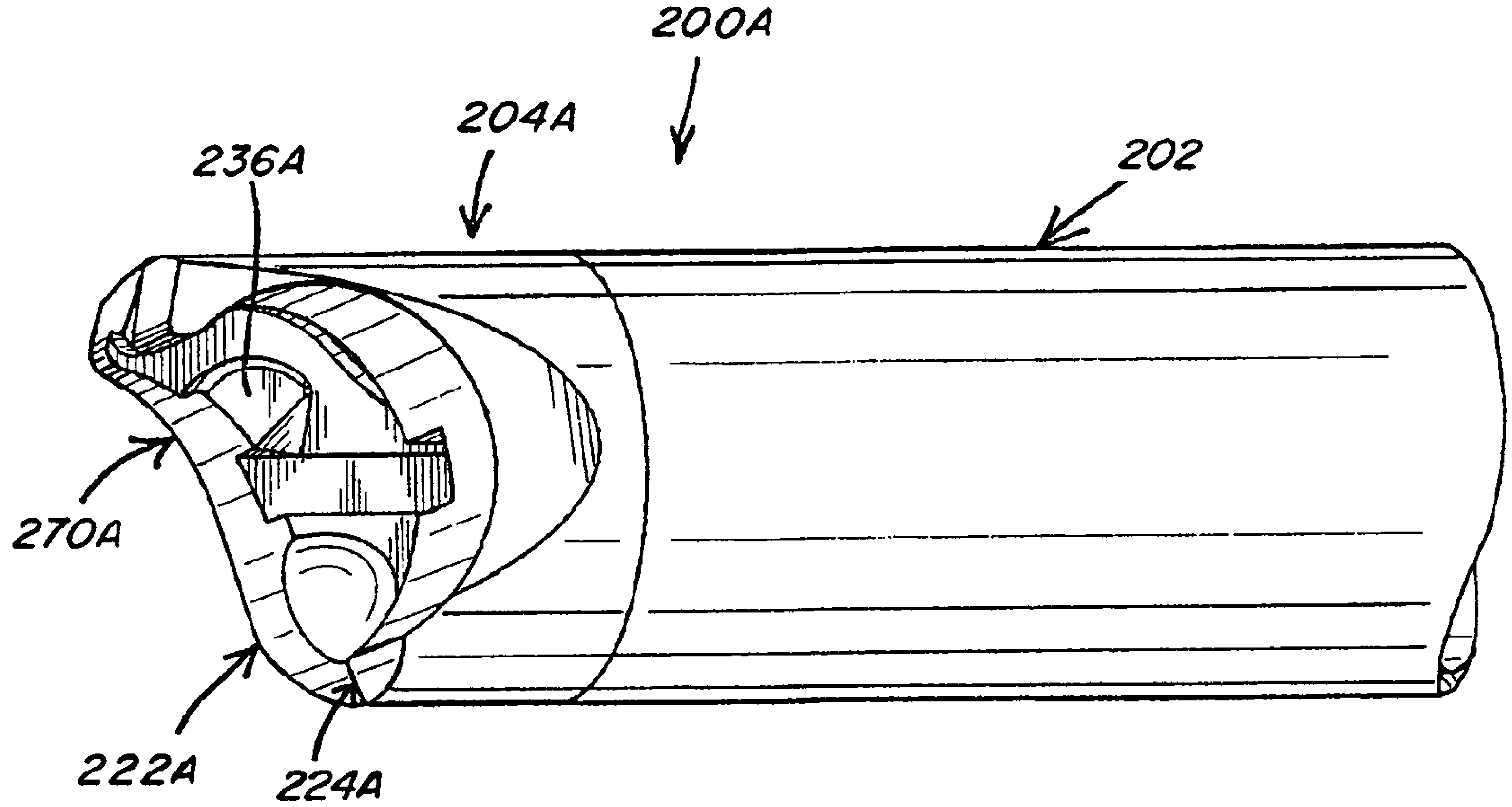
200A
204A
236A
202
270A
222A
224A

Fig. 39

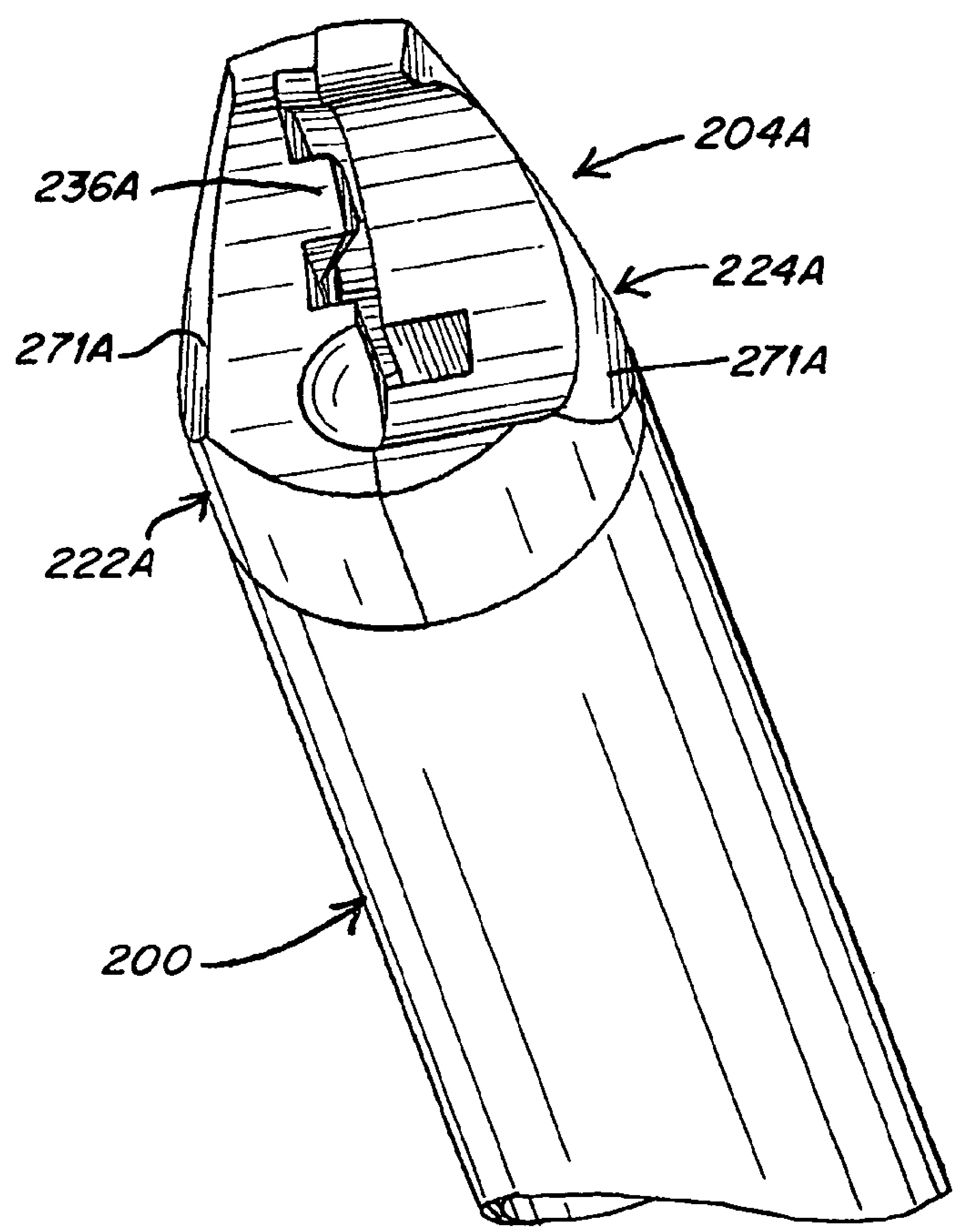
204A
236A
224A
271A
271A
222A
200

Fig. 40

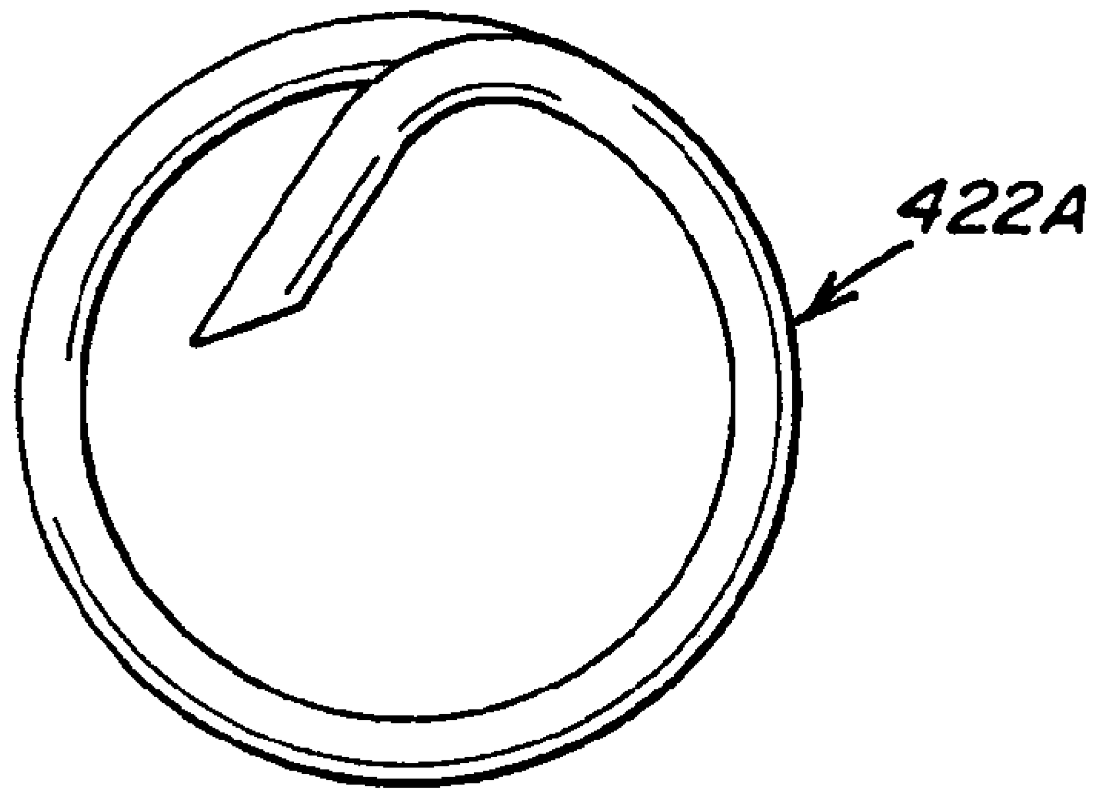

Fig. 41

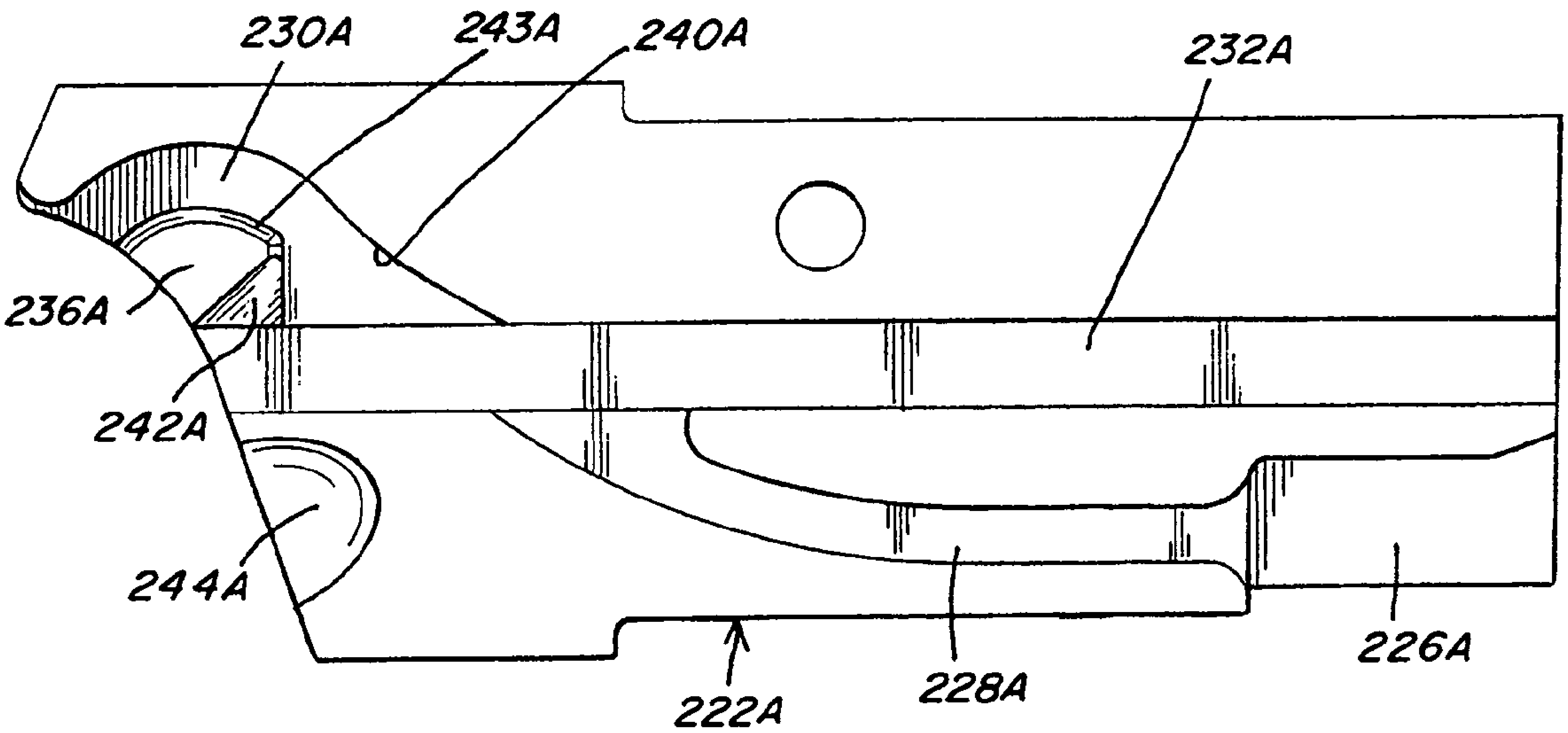

Fig. 42

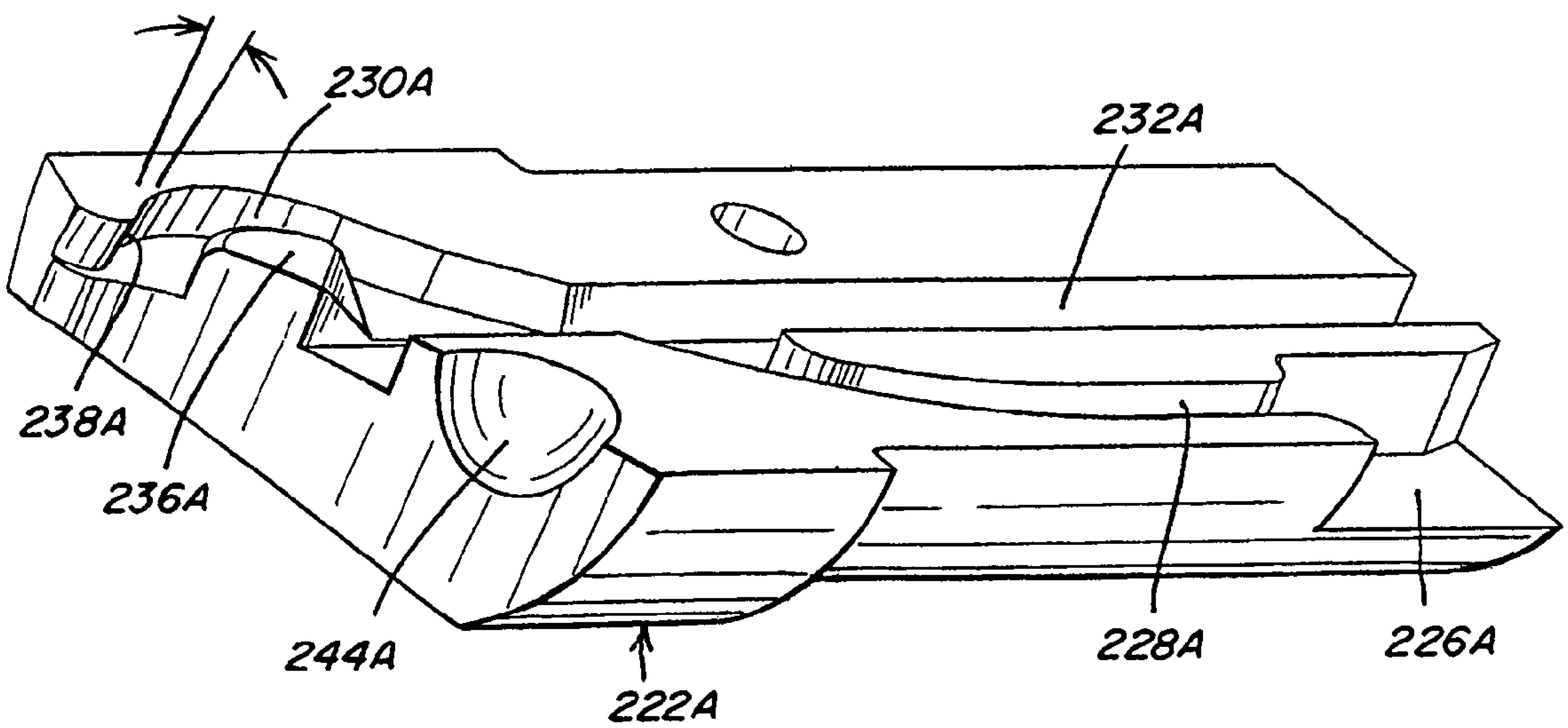

Fig. 43

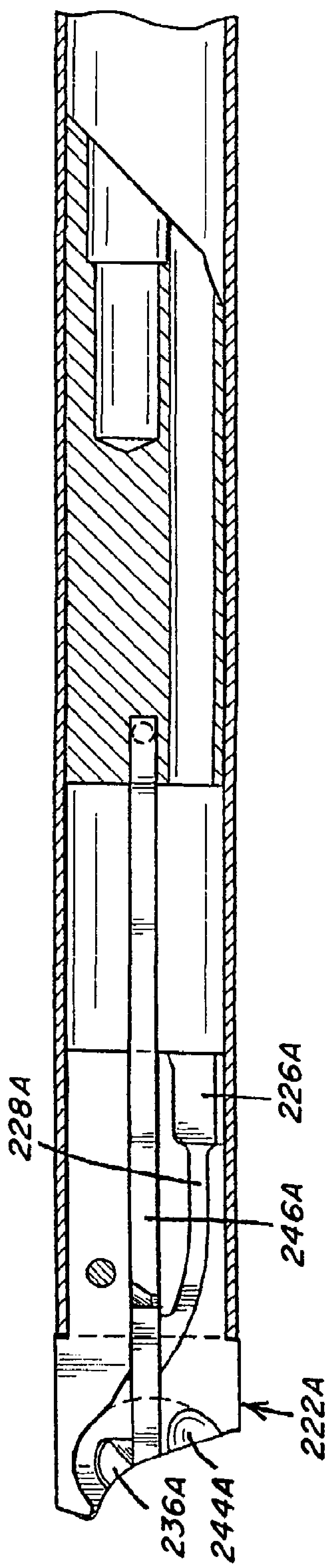

Fig. 44

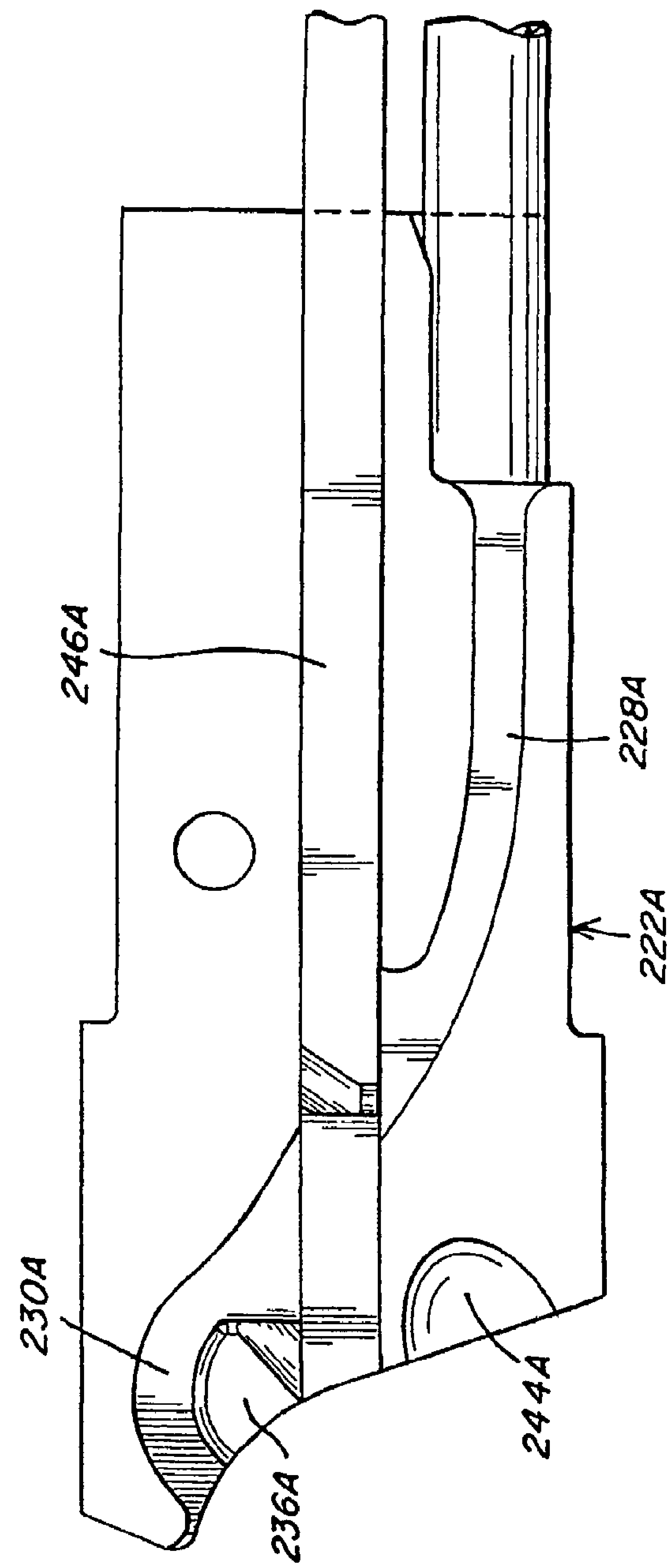

Fig. 45

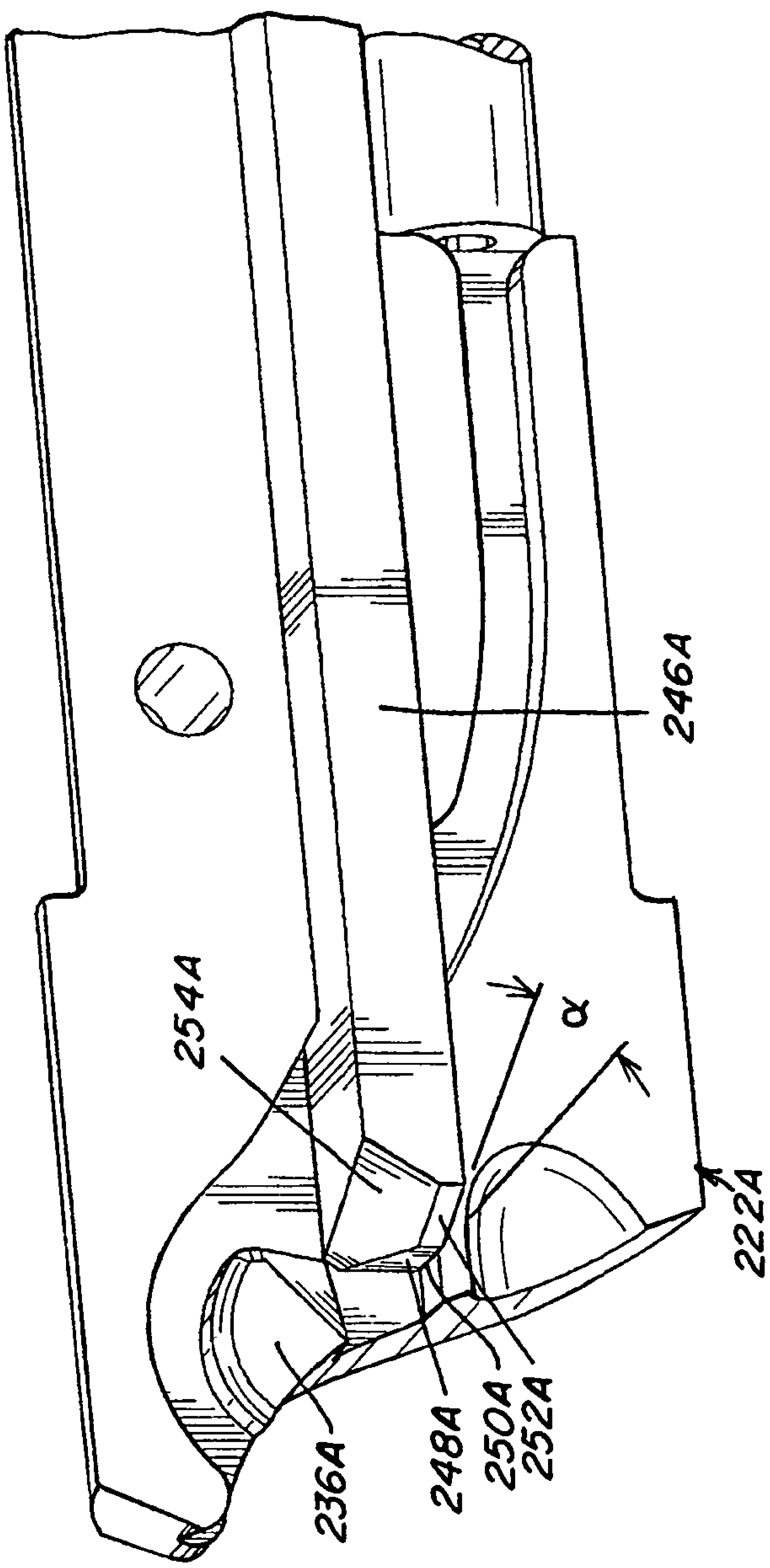

Fig. 46

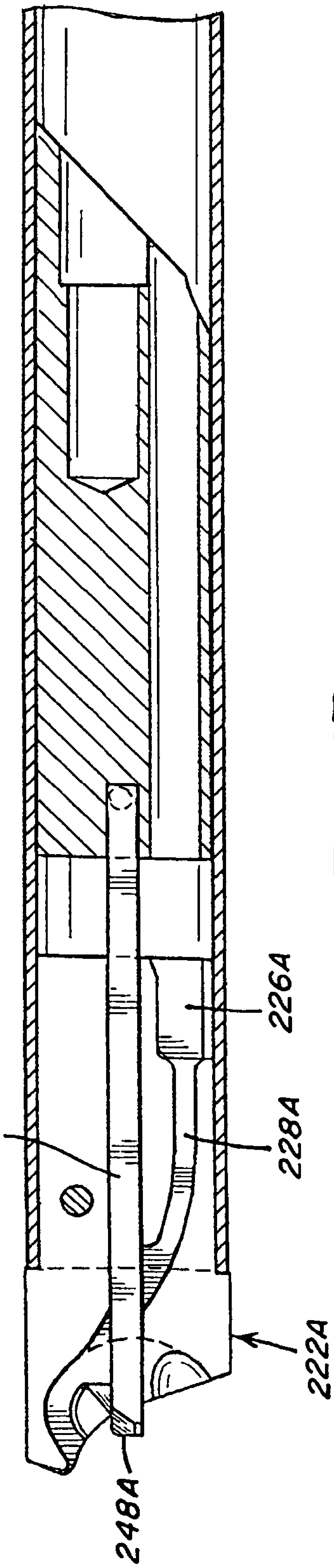

Fig. 47

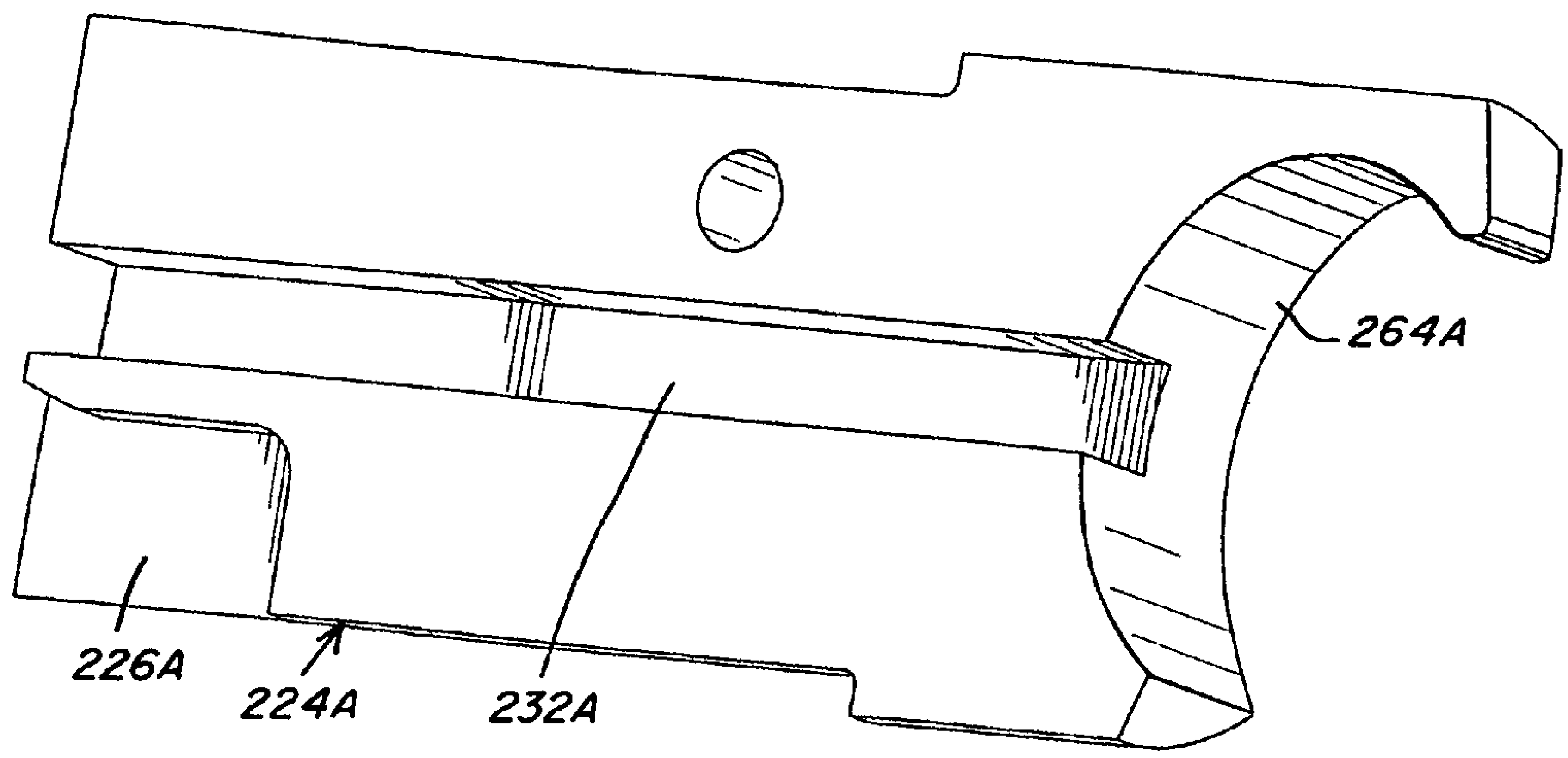

Fig. 48

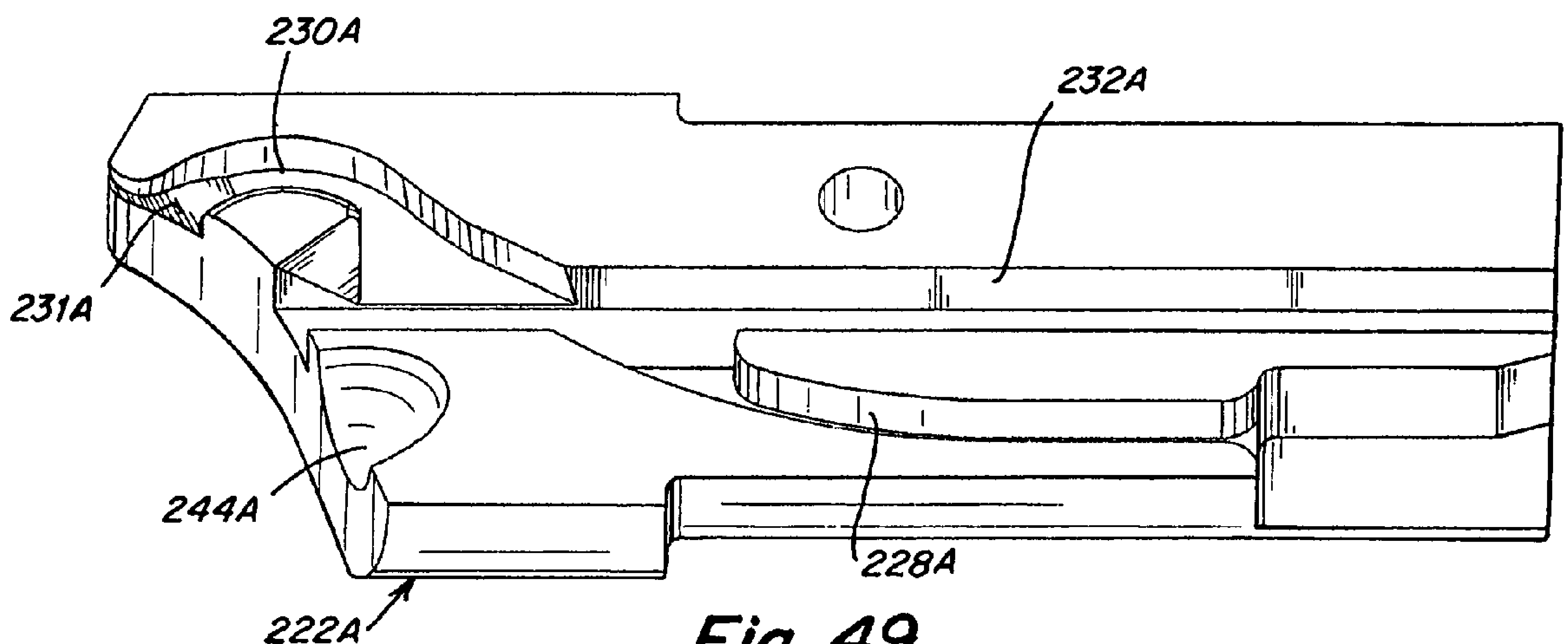

Fig. 49

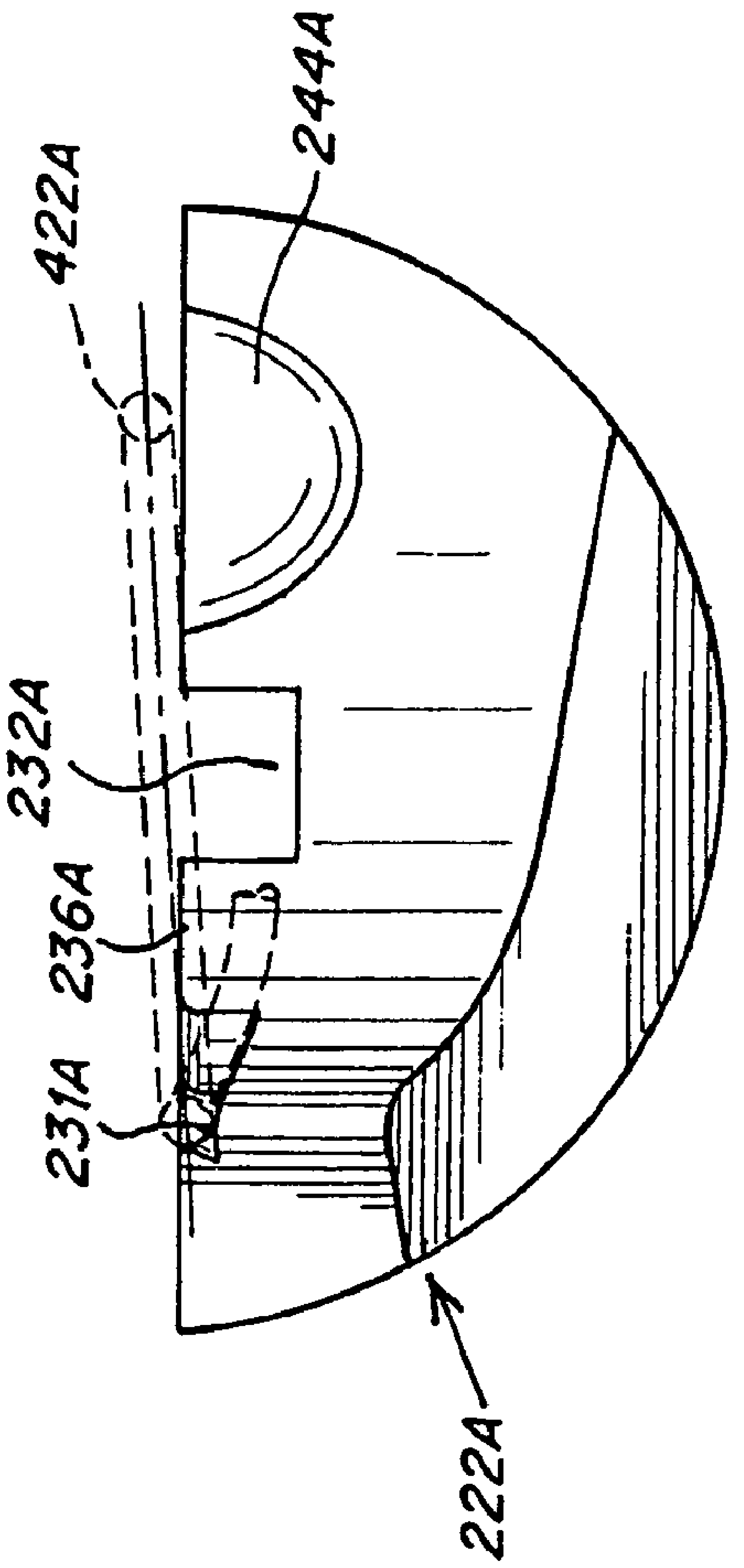

Fig. 50

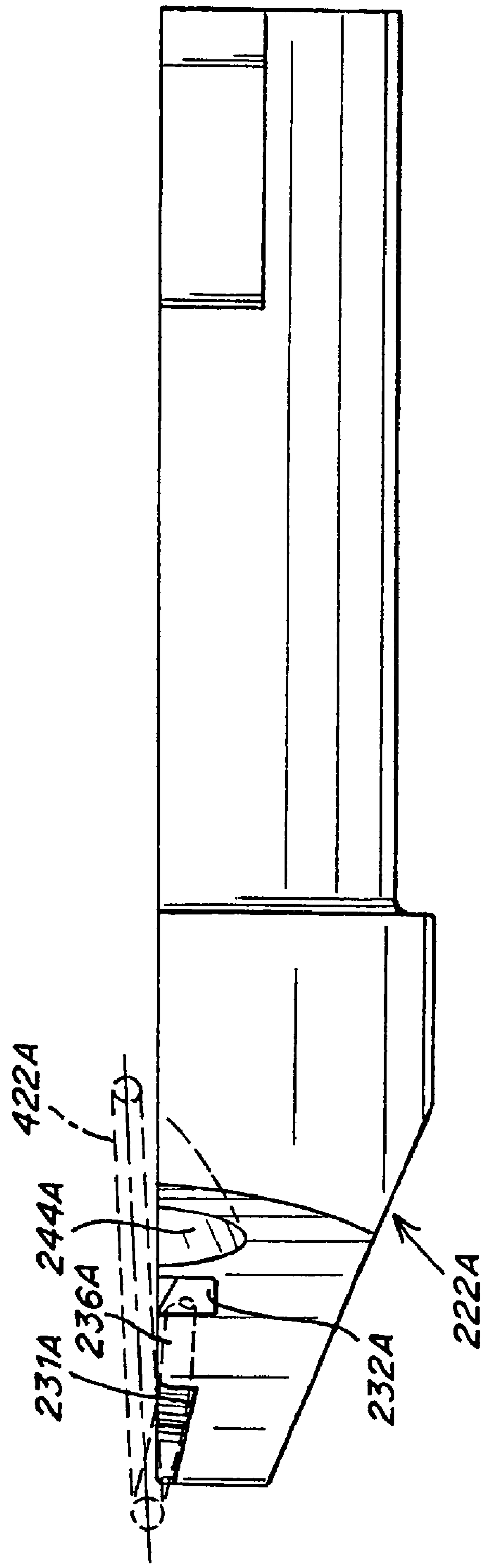

Fig. 51

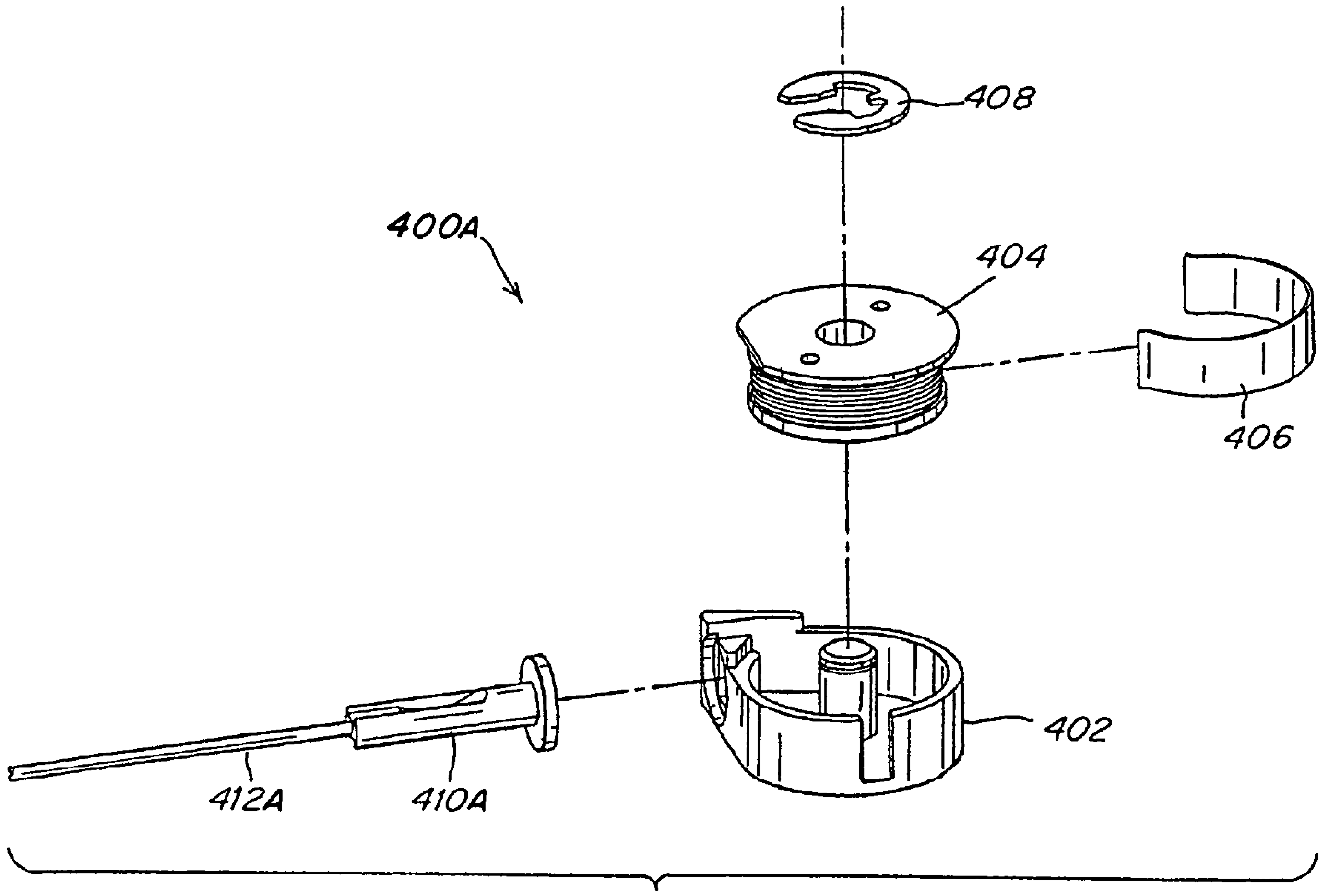

Fig. 52

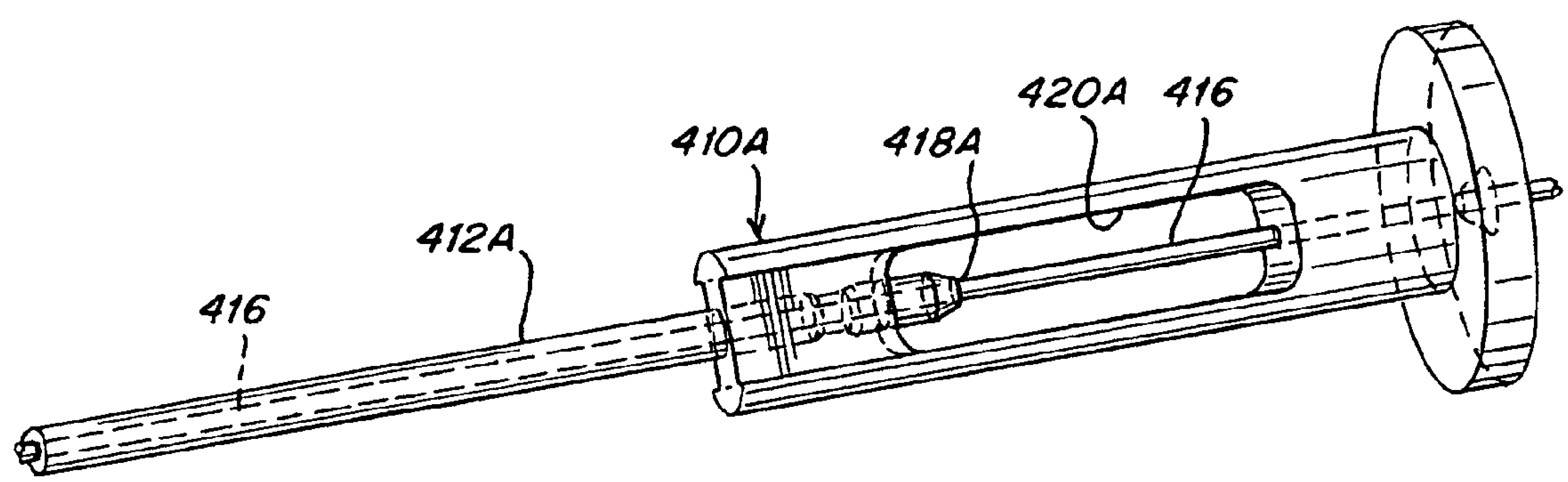

Fig. 53

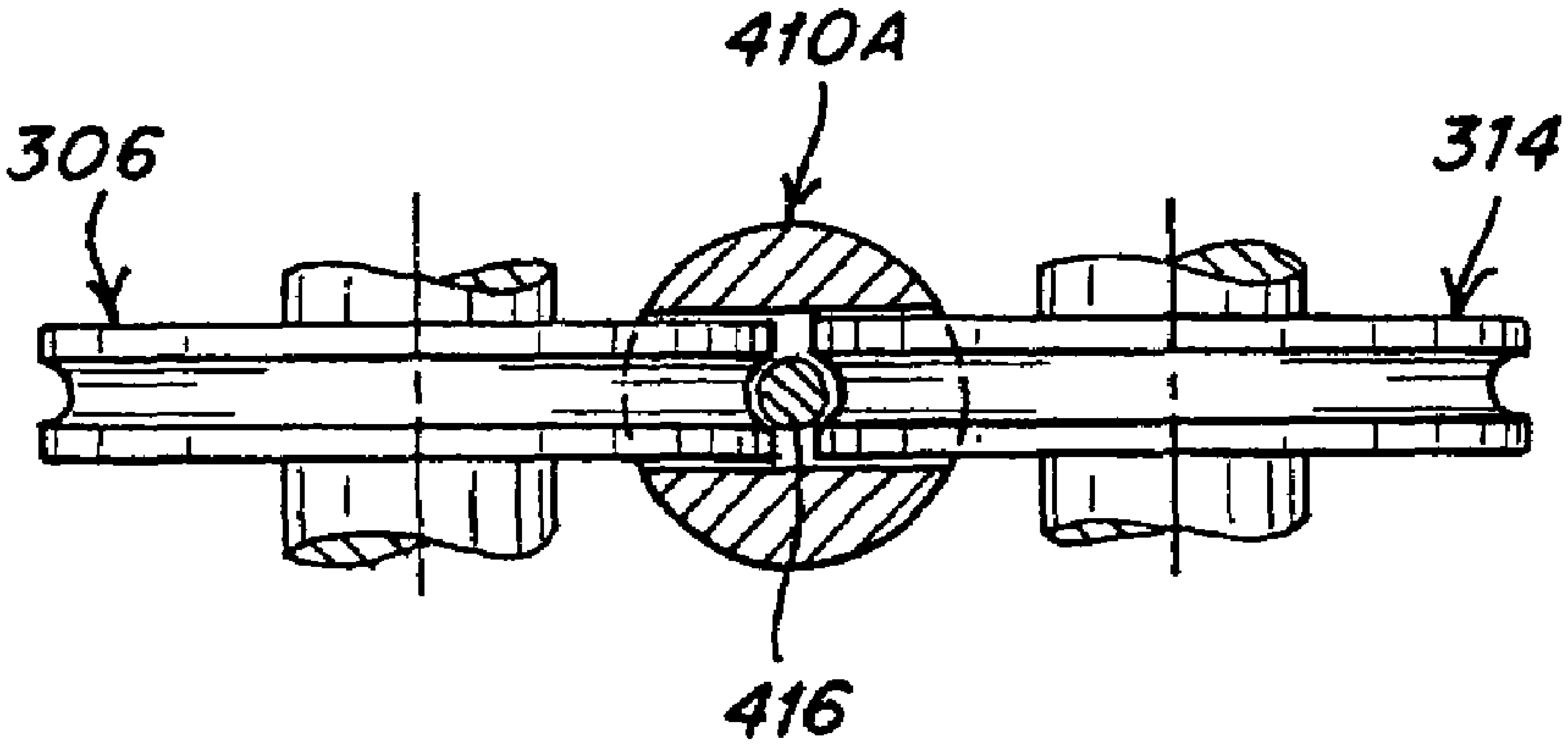

Fig. 54

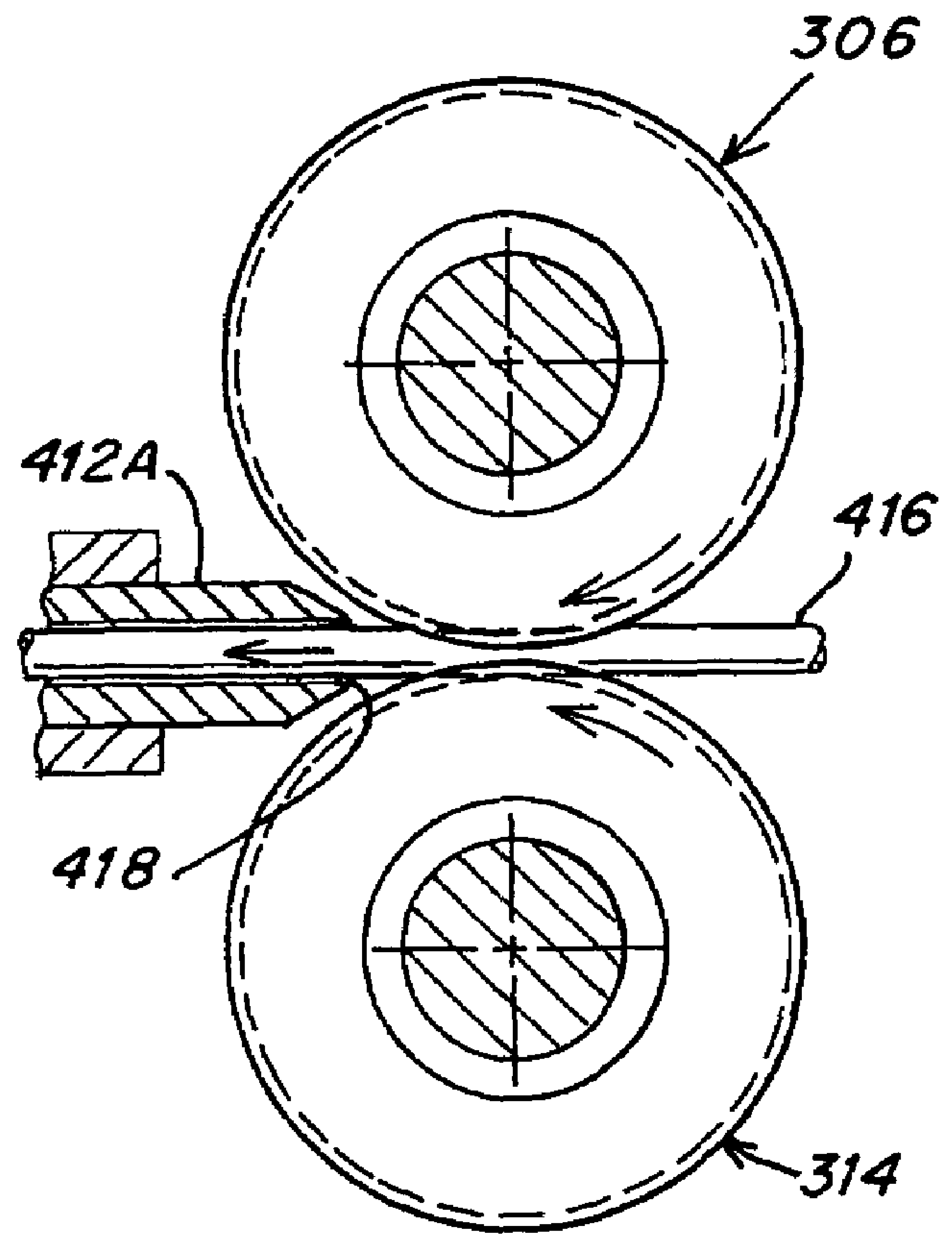

Fig. 55

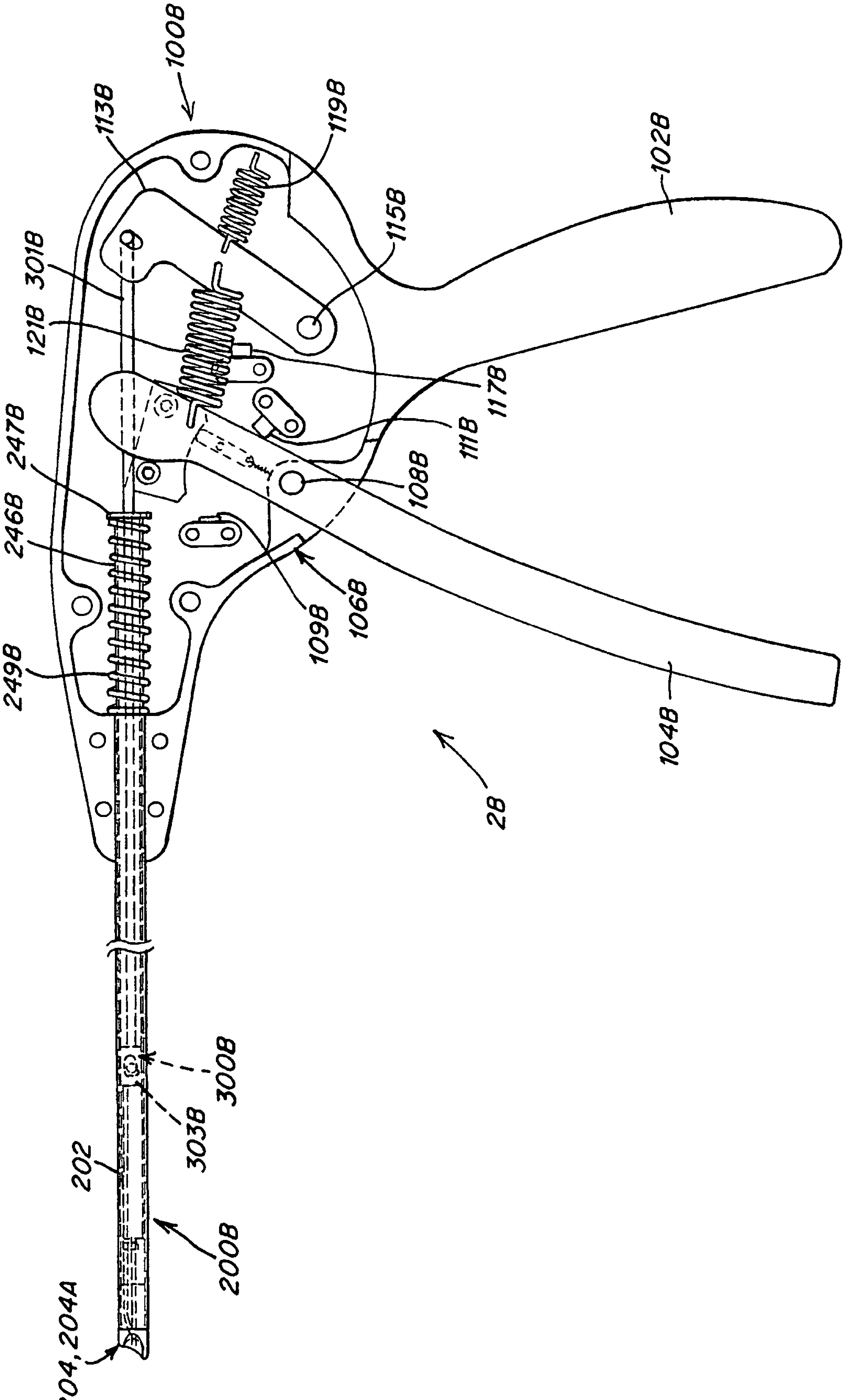
100B
113B
119B
102B
115B
301B
121B
117B
247B
111B
108B
246B
109B
106B
249B
104B
2B
300B
303B
202
200B
204,204A

Fig. 56

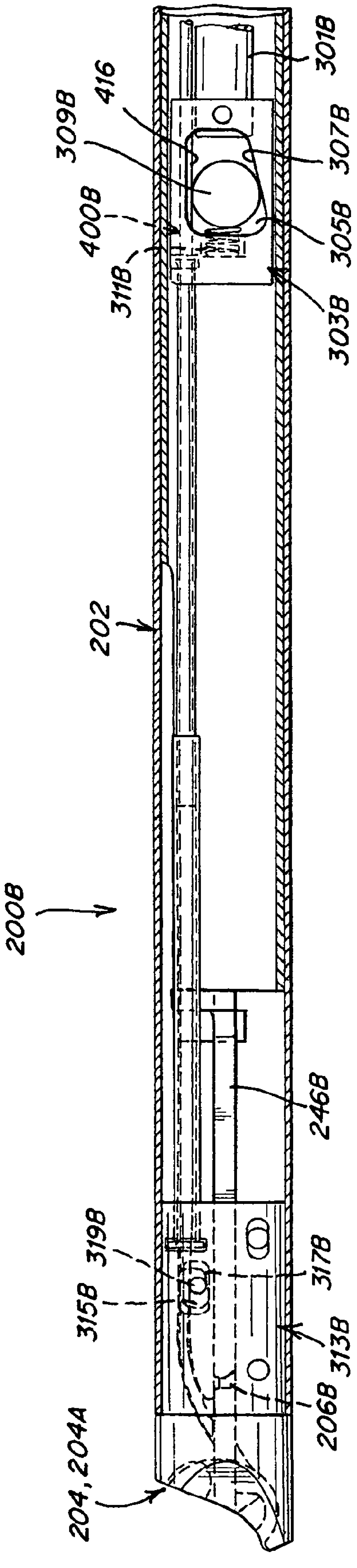

Fig. 57

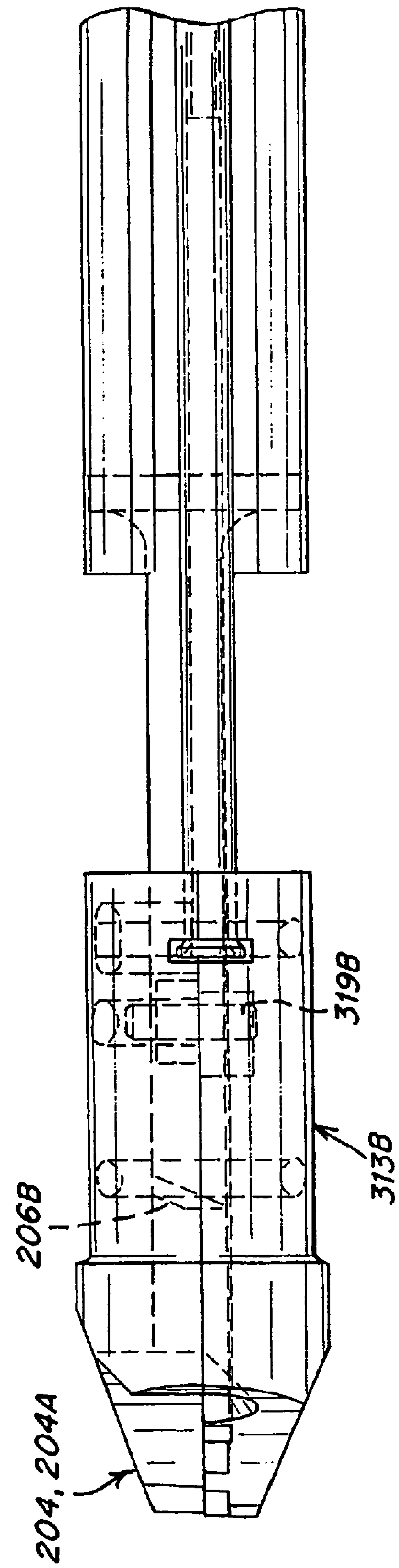

Fig. 57A

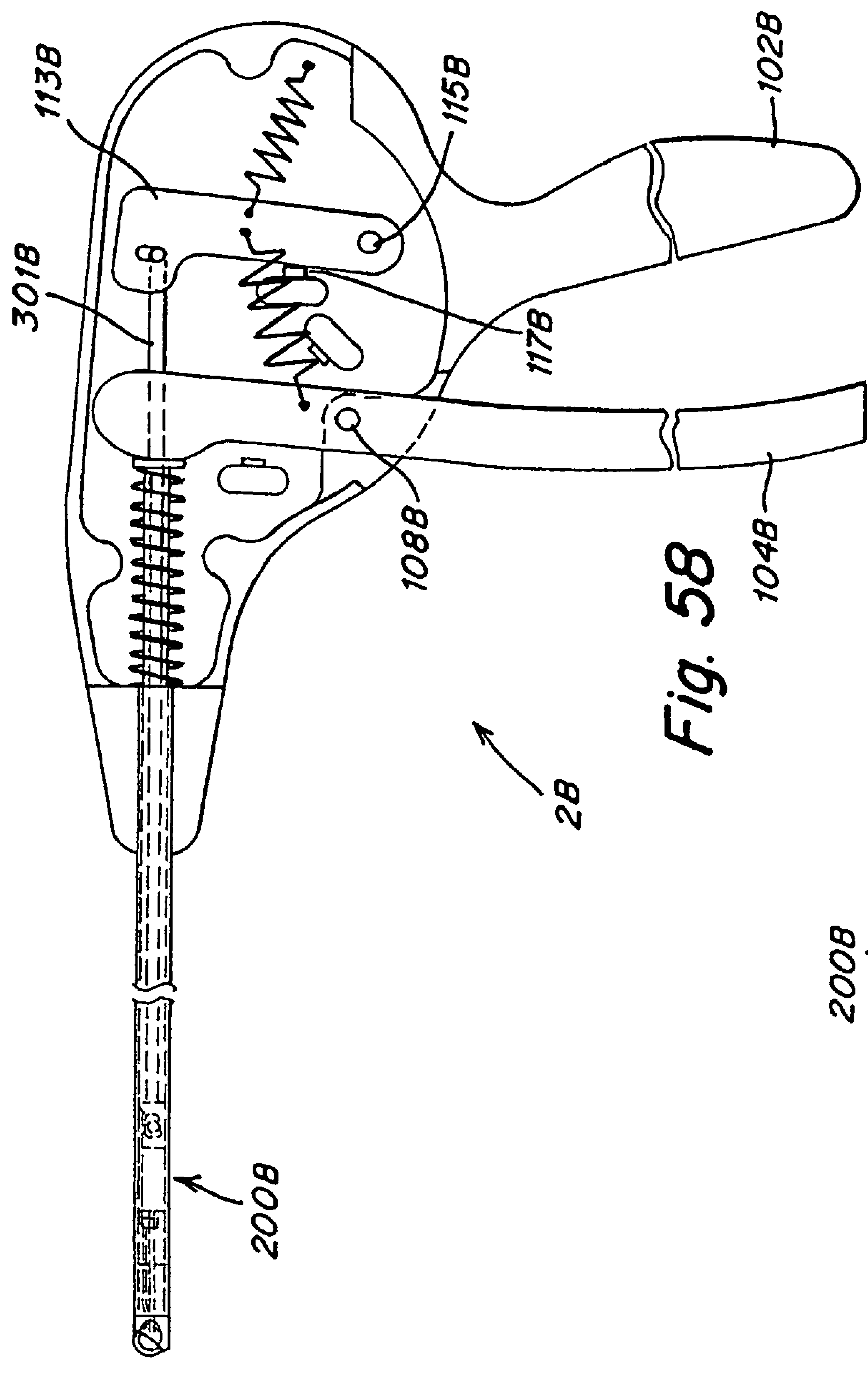
113B
115B
102B
301B
117B
108B
104B
2B
200B

Fig. 58

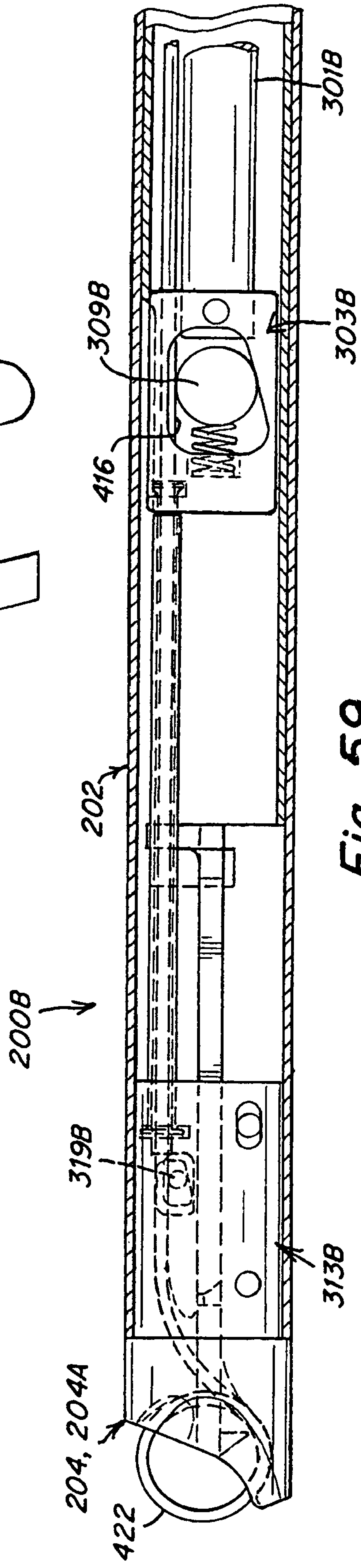
301B
309B
303B
416
202
200B
319B
313B
204, 204A
422

Fig. 59

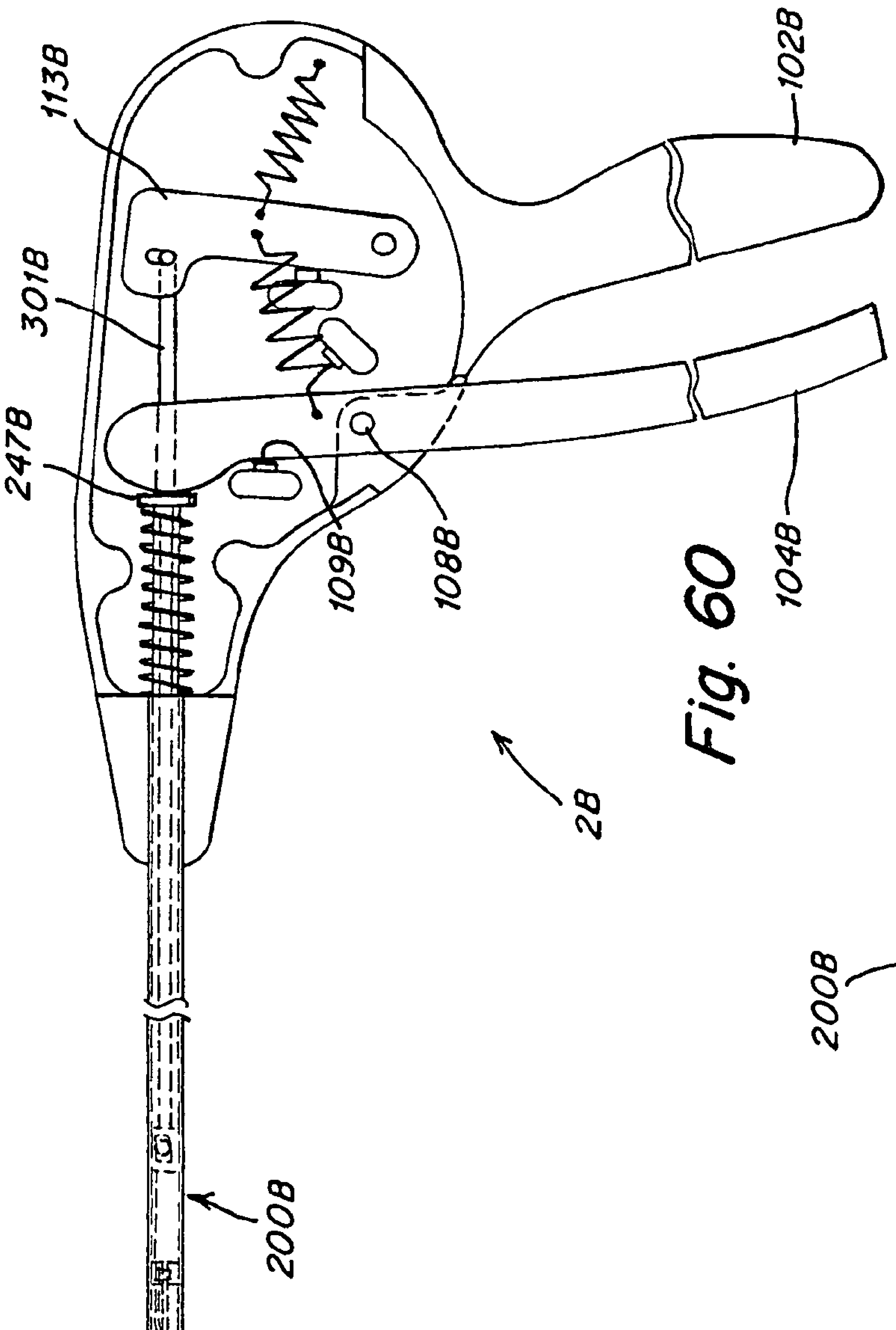
113B
102B
301B
247B
109B
108B
104B
2B
200B

Fig. 60

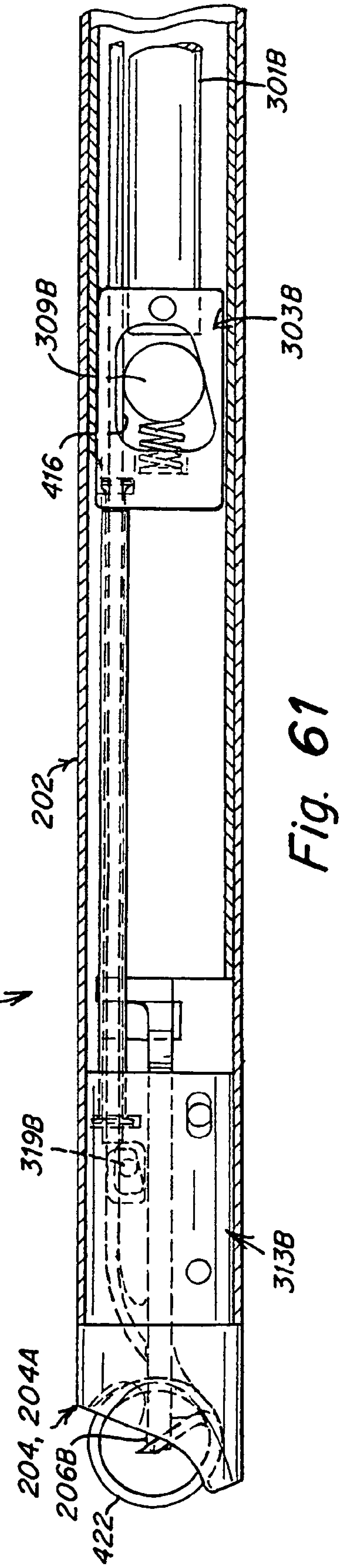
301B
309B
303B
416
202
200B
319B
313B
204, 204A
206B
422

Fig. 61

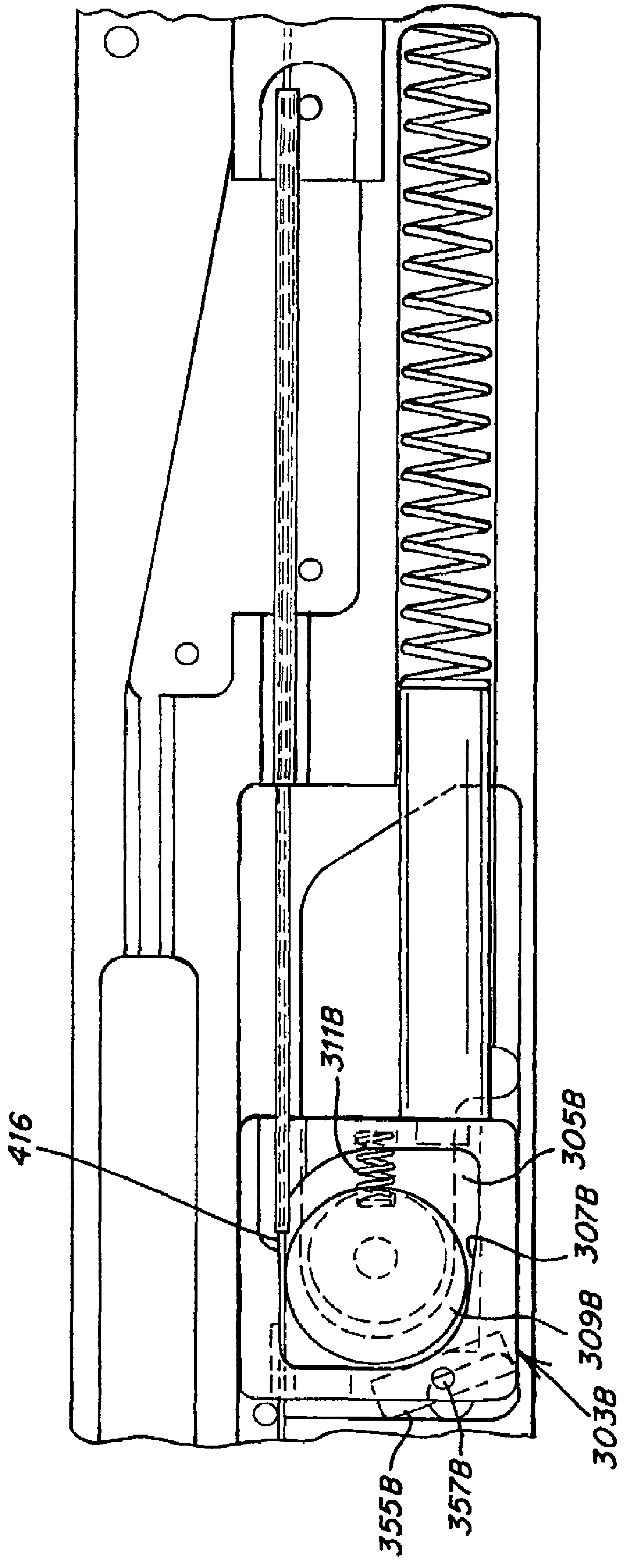

Fig. 62

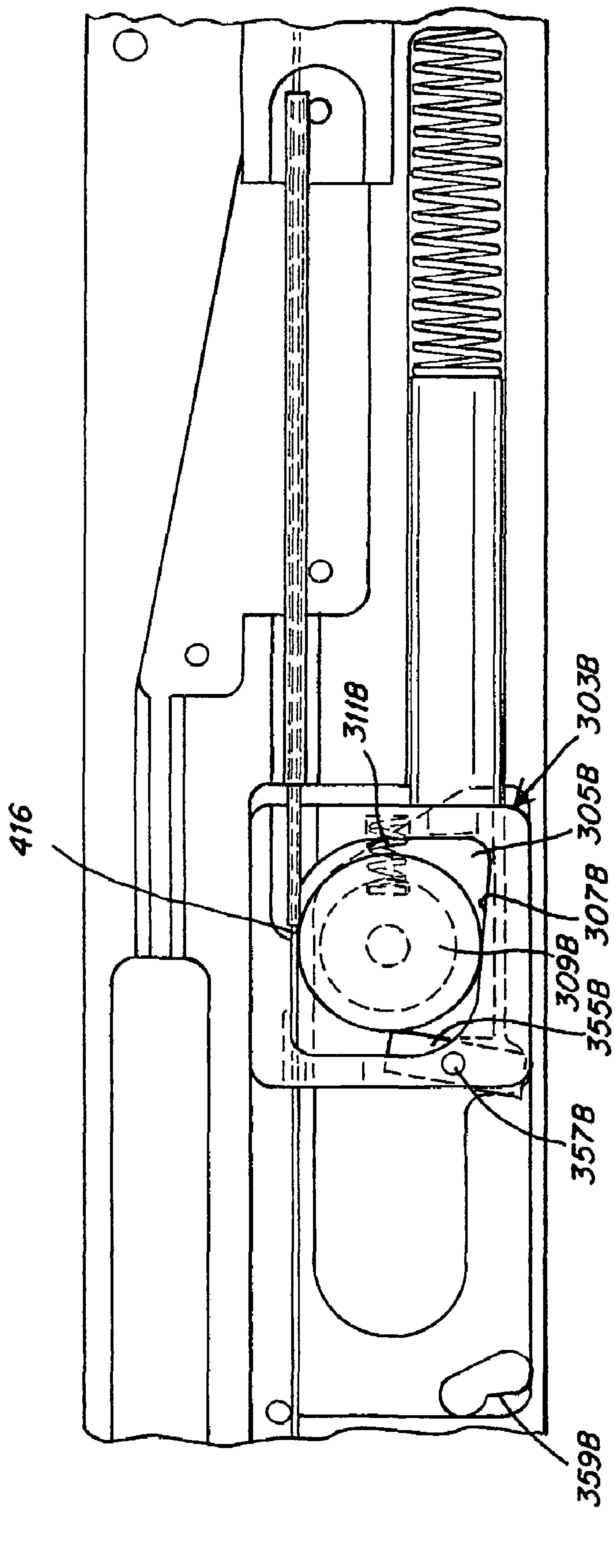

Fig. 63

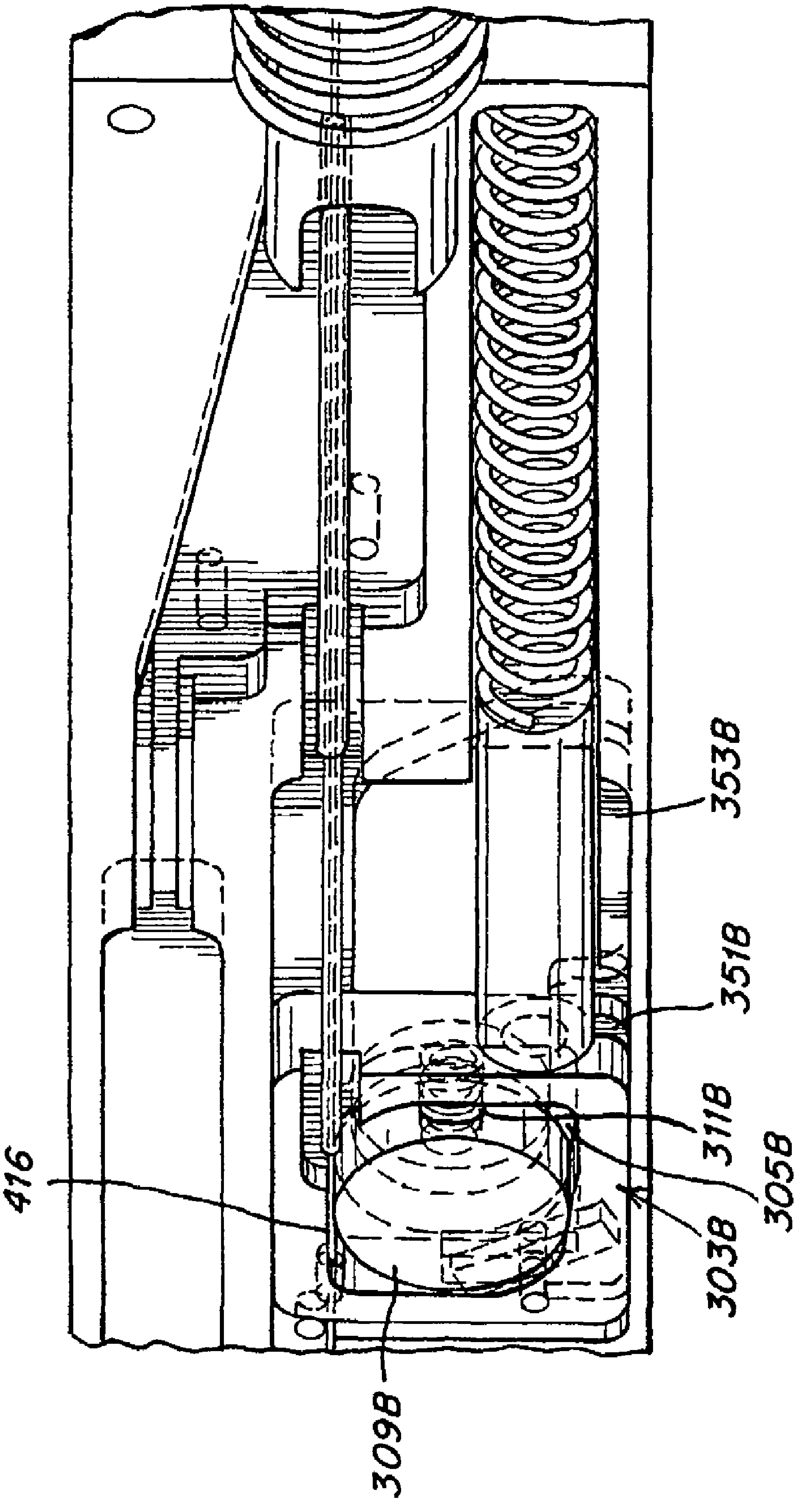

Fig. 64

SURGICAL SUTURING INSTRUMENT AND METHOD OF USE

REFERENCE TO PENDING PRIOR APPLICATIONS

This is a continuation-in-part of (1) pending prior U.S. patent application Ser. No. 10/352,600, filed Jan. 28, 2003 by Frederic P. Field et al. for SURGICAL SUTURING INSTRUMENT AND METHOD OF USE; (2) pending prior U.S. patent application Ser. No. 10/378,805, filed Mar. 4, 2003 by Gregory E. Sancoff et al. for SURGICAL SUTURING INSTRUMENT AND METHOD OF USE; and (3) pending prior U.S. patent application Ser. No. 10/396,927, filed Mar. 25, 2003 by Frederic P. Field et al. for SURGICAL SUTURING INSTRUMENT AND METHOD OF USE.

This patent application also claims benefit of pending prior U.S. Provisional Patent Application Ser. No. 60/381,601, filed May 17, 2002 by Joseph A. DiCarlo et al. for SURGICAL SUTURING SYSTEM AND METHOD OF USE.

The four above-identified patent applications are hereby incorporated herein by reference.

FIELD OF THE INVENTION

This invention relates to medical instruments and procedures in general, and more particularly to suturing instruments and methods for suturing.

BACKGROUND OF THE INVENTION

Suturing instruments are typically used to secure together two or more portions of a subject patient (e.g., tissue such as muscle or skin) or to attach an object to the patient (e.g., to attach a piece of surgical mesh to the abdominal wall of the patient during hernia repair surgery).

Certain suturing instruments employ a needle that precedes a length of suture material through a subject.

For example, U.S. Pat. Nos. 3,470,875; 4,027,608; 4,747,358; 5,308,353; 5,674,230; 5,690,653; 5,759,188; and 5,766,186 generally disclose suturing instruments in which a needle, with trailing suture material, is passed through a subject.

U.S. Pat. Nos. 4,890,615; 4,935,027; 5,417,700; and 5,728,112 generally disclose suturing instruments in which suture material is passed through the end of a hollow needle after that needle has been passed through a subject.

With all of the foregoing devices, a needle must be passed through the subject in order to deploy the suture. This has the disadvantage that the needle typically leaves a larger hole in the subject than is necessary to accommodate only the suture material itself. In this respect it should be appreciated that it is generally desirable to alter each portion of the material being sutured (e.g., tissue) as little as possible during the suturing process.

A suturing instrument has been devised which permits the suture material itself to pierce the subject without the use of a needle. However, this device does not permit adequate flexibility with regard to the type of fastening which may be effected.

More particularly, U.S. Pat. No. 5,499,990 discloses a suturing instrument having a pair of jaws at its distal end for clamping together two portions of a subject. A 0.25 mm stainless steel suturing wire is advanced to the distal end of the suturing instrument, whereupon the distal end of the suturing wire is caused to travel in a spiral direction so as to create stitches joining together the two portions of the subject. After the spiral is formed, the beginning and end portions of the suture may be bent toward the tissue in order to inhibit retraction of the suture wire into the tissue upon removal of the suturing instrument. The stainless steel wire is sufficiently firm to hold this locking set. In addition, after the spiral is formed, the radius of the deployed suture spiral may then be decreased by advancing an outer tube over a portion of the distal end of the instrument. Again, the stainless steel wire is sufficiently firm to hold this reducing set.

Unfortunately, however, such a system does not permit adequate flexibility with regard to the type of fastening which may be effected. More particularly, the suturing instrument of U.S. Pat. No. 5,499,990 must clamp the two portions of the subject between its two jaws in order to effect suturing. Such a construction can be inadequate where it is difficult or even impossible to clamp the two portions of the subject between the instrument's jaws, e.g., where the two portions of the subject are too thick to be spanned by the jaws, or where the angle of approach prevents the jaws from clamping together the two portions of the subject, etc.

U.S. Pat. No. 4,453,661 discloses a surgical instrument having a pair of jaws at its distal end for clamping together two portions of a subject and applying staples thereto. The staples are formed from the distal end of a length of wire. More particularly, the distal end of the wire is passed through a subject and thereafter contacts a die that causes the wire to bend, thereby forming the staple. The wire is sufficiently firm to take on the set imposed by the die. The staple portion is then cut away from the remainder of the wire by a knife.

Again, such a system suffers from the fact that it does not permit adequate flexibility with regard to the type of fastening which may be effected, since the surgical instrument must clamp the two portions of the subject between its two jaws in order to effect stapling, and this can be difficult or even impossible to achieve in certain circumstances, e.g., where the two portions of the subject are too thick to be spanned by the jaws, or where the angle of approach prevents clamping, etc.

There is a need, therefore, for a new suturing device that permits minimally disruptive suturing and provides increased flexibility in the application of the suture material.

SUMMARY OF THE INVENTION

The present invention comprises a novel device and method for deploying a flexible elongated element through a subject so as to effect suturing.

In one embodiment of the invention, the device includes a proximal end and a distal end, and an advancement unit for longitudinally advancing the flexible elongated element toward the distal end of the device such that a distal end of the flexible elongated element may exit from the distal end of the device with sufficient force to pass through the subject. The device also includes a curved die at the distal end of the device for imparting a looping configuration to portions of the flexible elongated element exiting the distal end of the device, and a curved guide at the distal end of the device for receiving the looped flexible elongated element as it returns to the distal end of the device. In a further feature of the invention, a cutting mechanism is provided to permit the looped flexible elongated element to be separated from the remainder of the flexible elongated element. And in a further feature of the invention, the cutting mechanism is adapted to deform the trailing end of the looped flexible elongated element so that the trailing end is forced distally, toward the subject being sutured.

In another form of the invention, there is provided a suturing instrument for joining a first portion of material to a second portion of material, the suturing instrument comprising:

a handle;

an end effector mounted on the handle and defining therein:

a channel for supporting suture wire, the channel being curved to impart a looping configuration to portions of the suture wire passed therethrough;

an end recess adapted to receive the looped suture wire emerged from the channel; and

a passageway for supporting a cutting bar, the passageway intersecting the channel so as to create an island between the channel and the passageway;

a wire advancing actuator mounted on the handle for moving the suture wire through the channel, through the material first and second portions and back into the end recess, the wire advancing actuator comprising a sliding cage adapted for distal and proximal movement within the handle, the sliding cage comprising a cam and a cam follower, and further wherein (1) distal movement of the sliding cage causes the cam follower to move along the cam so as to bindingly engage the suture wire and drive it distally, and (2) proximal movement of the sliding cage causes the cam follower to move along the cam so as to disengage from binding engagement with the suture wire;

a cutting bar movably disposed in the passageway for selectively engaging the suture wire, the cutting bar being adapted to (1) cut the looped suture wire from the remaining portions of the suture wire; and (2) bend the trailing end of the looped suture wire around, and lift the looped suture wire over, the island; and

a cutting bar actuator mounted on the handle for moving the cutting bar into engagement with the suture wire.

In another form of the invention, there is provided a method for joining a first portion of material to a second portion of material, the method comprising:

providing a suturing instrument comprising:

a handle;

an end effector mounted on the handle and defining therein:

a channel for supporting suture wire, the channel being curved to impart a looping configuration to portions of the suture wire passed therethrough;

an end recess adapted to receive the looped suture wire emerged from the channel; and

a passageway for supporting a cutting bar, the passageway intersecting the channel so as to create an island between the channel and the passageway;

a wire advancing actuator mounted on the handle for moving the suture wire through the channel, through the material first and second portions and back into the end recess, the wire advancing actuator comprising a sliding cage adapted for distal and proximal movement within the handle, the sliding cage comprising a cam and a cam follower, and further wherein (1) distal movement of the sliding cage causes the cam follower to move along the cam so as to bindingly engage the suture wire and drive it distally, and (2) proximal movement of the sliding cage causes the cam follower to move along the cam so as to disengage from binding engagement with the suture wire;

a cutting bar movably disposed in the passageway for selectively engaging the suture wire, the cutting bar being adapted to (1) cut the looped suture wire from the remaining portions of the suture wire; and (2) bend the trailing end of the looped suture wire around, and lift the looped suture wire over, the island; and

a cutting bar actuator mounted on the handle for moving the cutting bar into engagement with the suture wire;

positioning the end effector against at least one of the portions to be joined;

moving the suture wire through the channel, through the material first and second portions and back into the end recess; and

moving the cutting bar in the passageway so as to (1) cut the looped suture wire from the remaining portions of the suture wire; and (2) bend the trailing end of the looped suture wire around, and lift the looped suture wire over, the island.

In another form of the invention, there is provided a suturing instrument for joining a first portion of material to a second portion of material, the suturing instrument comprising:

a handle;

an end effector mounted on the handle and defining therein:

a channel for supporting suture wire, the channel being curved to impart a looping configuration to portions of the suture wire passed therethrough;

an end recess adapted to receive the looped suture wire emerged from the channel; and

a passageway for supporting a cutting bar, the passageway intersecting the channel so as to create an island between the channel and the passageway;

a wire advancing actuator mounted on the handle for moving the suture wire through the channel, through the material first and second portions and back into the end recess, the wire advancing actuator comprising a sliding cage adapted for distal and proximal movement within the handle, the sliding cage comprising a cam and a cam follower, and further wherein (1) distal movement of the sliding cage to a first extent causes the cam follower to move along the cam so as to bindingly engage the suture wire and drive it distally, and (2) distal movement of the sliding cage to a second extent causes the cam follower to move along the cam so as to disengage from binding engagement with the suture wire;

a cutting bar movably disposed in the passageway for selectively engaging the suture wire, the cutting bar being adapted to (1) cut the looped suture wire from the remaining portions of the suture wire; and (2) bend the trailing end of the looped suture wire around, and lift the looped suture wire over, the island; and

a cutting bar actuator mounted on the handle for moving the cutting bar into engagement with the suture wire.

In another form of the invention, there is provided a method for joining a first portion of material to a second portion of material, the method comprising:

providing a suturing instrument comprising:

a handle;

an end effector mounted on the handle and defining therein:

a channel for supporting suture wire, the channel being curved to impart a looping configuration to portions of the suture wire passed therethrough;

an end recess adapted to receive the looped suture wire emerged from the channel; and

a passageway for supporting a cutting bar, the passageway intersecting the channel so as to create an island between the channel and the passageway;

a wire advancing actuator mounted on the handle for moving the suture wire through the channel, through the material first and second portions and back into the end recess; the wire advancing actuator comprising a sliding cage adapted for distal and proximal movement within the handle, the sliding cage comprising a cam and a cam follower, and further wherein (1) distal movement of the sliding cage to a first extent causes the cam follower to move along the cam so as to bindingly engage the suture wire and drive it distally, and (2) distal movement of the sliding cage to a second extent causes the cam follower to move along the cam so as to disengage from binding engagement with the suture wire;

a cutting bar movably disposed in the passageway for selectively engaging the suture wire, the cutting bar being adapted to (1) cut the looped suture wire from the remaining portions of the suture wire; and (2) bend the trailing end of the looped suture wire around, and lift the looped suture wire over, the island; and

a cutting bar actuator mounted on the handle for moving the cutting bar into engagement with the suture wire;

positioning the end effector against at least one of the portions to be joined;

moving the suture wire through the channel, through the material first and second portions and back into the end recess; and

moving the cutting bar in the passageway so as to (1) cut the looped suture wire from the remaining portions of the suture wire; and (2) bend the trailing end of the looped suture wire around, and lift the looped suture wire over, the island.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiments of the invention, which is to be considered together with the accompanying drawings wherein like numbers refer to like parts, and further wherein:

FIG. **1** is a side view showing a suturing instrument formed in accordance with the present invention;

FIGS. **2**–**5** are various views showing various details of the suturing instrument's handle assembly;

FIGS. **6**–**17** are various views showing various details of the suturing instrument's cannula assembly;

FIGS. **18**–**21** are various views showing various details of the suturing instrument's wire drive assembly;

FIGS. **22**–**25** are various views showing various details of the suturing instrument's wire supply cartridge;

FIG. **26** is a schematic view showing two portions being secured to one another with a suture loop deployed by the suturing instrument;

FIGS. **27**–**33** show various steps in a suturing operation conducted with the suturing instrument;

FIG. **34** is a schematic view showing an alternative form of tissue attachment being effected with the suturing instrument;

FIGS. **35**–**37** are schematic side views illustrating the interrelationship between the geometry of the cannula assembly's end effector portion and the leading tip of the suture wire;

FIG. **38** is a schematic view showing the suturing instrument securing a prosthetic cardiac valve to vascular tissue with suture loops;

FIGS. **39** and **40** are schematic views of a cannula assembly of an alternative suturing instrument;

FIG. **41** is an illustration of a modified suture loop formed by the cannula assembly of the alternative suturing instrument shown in FIGS. **39** and **40**;

FIGS. **42**–**51** are schematic views of an end effector of the alternative suturing instrument shown in FIGS. **39** and **40**;

FIGS. **52**–**55** are schematic views of an alternative wire supply cartridge; and

FIG. **56** is a schematic side view of a suturing instrument which comprises another form of the present invention, with the instrument being shown in a first state of operation;

FIG. **57** is an enlarged schematic side view showing the distal end of the suturing instrument shown in FIG. **56**;

FIG. **57**A is an enlarged schematic top view showing the distal end of the suturing instrument shown in FIG. **56**;

FIG. **58** is a schematic side view showing the suturing instrument of FIG. **56** in a second state of operation;

FIG. **59** is an enlarged schematic side view showing the distal end of the suturing instrument shown in FIG. **58**;

FIG. **60** a schematic side view showing the suturing instrument of FIG. **56** in a third state of operation;

FIG. **61** is an enlarged schematic side view showing the distal end of the suturing instrument shown in FIG. **60**; and

FIGS. **62**–**64** are schematic views showing another form of wire drive assembly, with FIG. **62** being a side view with the sliding cage in a retracted position, FIG. **63** being a side view with the sliding cage in an extended position, and FIG. **64** being a perspective view with the sliding cage in a retracted position.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Overview

Looking first at FIGS. **1**–**5**, there is shown a suturing instrument **2** which comprises one preferred embodiment of the present invention. Suturing instrument **2** generally comprises a handle assembly **100**, a cannula assembly **200**, a wire drive assembly **300** (FIG. **5**) and a wire supply cartridge **400**, as will hereinafter be described in further detail.

Among other things, handle assembly **100** comprises a handle **102** and a lever **104**, and cannula assembly **200** comprises a shaft **202**, an end effector **204** and a wire cutting mechanism **206**, as will also hereinafter be described in further detail.

As will be discussed in further detail below, generally during use, the suturing instrument's end effector **204** is positioned adjacent to the subject which is to be sutured. Then lever **104** is squeezed towards handle **102**, causing wire drive assembly **300** to draw suture wire out of wire supply cartridge **400** and push the suture wire distally through cannula assembly **200** to end effector **204**, where the suture wire exits the instrument with sufficient force to pass through the subject. End effector **204** includes a curved die for imparting a looping configuration to the portions of the suture wire exiting the distal end of the instrument, and a curved guide for receiving the looped suture wire as it returns to the distal end of the instrument. The looped suture wire may then be cut off, at end effector **204**, from the remaining suture wire that extends back through the suturing instrument. Such cutting is preferably automatically effected by wire cutting mechanism **206** at the conclusion of the lever's stroke.

As will be discussed in further detail below, wire supply cartridge **400** may be supplied separately from suturing instrument **2**, with wire supply cartridge **400** being loaded into suturing instrument **2** prior to commencing a suturing operation. As will also be discussed in further detail below, wire supply cartridge **400** may be disposable, such that the cartridge may be discarded after use.

Handle Assembly **100**

Still looking at FIGS. **1–5**, handle assembly **100** comprises a housing **106**, with the aforementioned handle **102** being fixedly attached to housing **106** and the aforementioned lever **104** being pivotally connected to housing **106** by a pivot pin **108**.

The inner end of lever **104** includes a slot **110** for receiving a roll pin **112** therein. Roll pin **112** is also secured to a rack **114**. Rack **114** is connected to a compression spring **116** at its distal end. Rack **114** includes a length of teeth **118** intermediate its length, followed by a smooth wall **120** adjacent to its proximal end. As a result of this construction, compression spring **116** normally biases rack **114** proximally, so that lever **104** is biased away from handle **102**; however, lever **104** may be squeezed toward handle **102** so as to overcome the force of spring **116**, whereby to move rack **114** distally. A pawl **122** (FIG. **3**), riding on lever **104** and engaging a set of teeth **124**, ensures that lever **104** cannot return to its proximal starting position without moving through one complete stroke. A removable shroud **126** selectively closes off the proximal end of housing **106**. The removable nature of shroud **126** permits a fresh wire supply cartridge **400** to be loaded into the suturing instrument and an exhausted wire supply cartridge to be removed from the instrument, as will hereinafter be discussed in further detail.

Cannula Assembly **200**

Cannula assembly **200** is shown in greater detail in FIGS. **6–16**. As noted above, cannula assembly **200** (FIG. **6**) comprises shaft **202**, end effector **204** and wire cutting mechanism **206**.

More particularly, shaft **202** comprises a tube **208** having a distal end **210** and a proximal end **212**. A mount **214** is secured to tube **208** near its proximal end whereby shaft **202**, and hence the entire cannula assembly **200**, may be removably attached to housing **106** of handle assembly **100**. Mount **214** includes a flushing port **216** (FIG. **7**), communicating with the interior of tube **208** via an opening **218** (FIG. **8**), for cleaning the interior of cannula assembly **200**. A cap **220** selectively closes off flushing port **216**.

End effector **204** is secured to the distal end of tube **208**.

End effector **204** is configured so as to form a modified suture loop **422** (FIG. **26**), sometimes referred to as a "suture clip" or a "Q-form loop" or a "Q-form clip", as will hereinafter be discussed.

More particularly, end effector **204** comprises a fixed first portion **222** (FIGS. **10**, **11** and **12**) and a fixed second portion **224** (FIGS. **10**, **11**, and **17**).

As seen in FIG. **12**, fixed first portion **222** includes a first channel **226** for receiving the distal end of the aforementioned wire supply cartridge **400**, a smaller diameter second channel **228** for supporting suture wire as the suture wire emerges from wire supply cartridge **400**, and a third channel **230** for receiving the suture wire after the suture wire passes by cutting bar channel **232** and for imparting a selected curvature to the suture wire, whereby to form the suture loop, as will hereinafter be discussed in further detail. Second channel **228** and third channel **230** are coplanar. In addition to the foregoing, material is removed from fixed first portion **222** at the location **234** so as to effectively form an island **236** at the distal end of end effector **204**.

In order to assist the controlled retention of suture wire during its travel within second channel **228** and third channel **230**, one or both of these channels may be given an undercut profile such as the dovetail profile **238** shown in FIG. **13** with respect to third channel **230**. At the same time, in order to minimize harmful friction between the suture wire and fixed first portion **222**, second channel **230** may be widened slightly at locations other than **240** (FIG. **12**); locations **240** are, for this particular clip form, the operative contact points for effecting wire bending (in this respect it should be appreciated that other particular clip forms may have other contact points). In addition, in order to facilitate the release of a formed suture clip from the instrument, the proximal end of island **236** may be relieved slightly at **242** (FIG. **12**).

In addition to the foregoing, fixed first portion **222** may be relieved as shown as **244** (FIG. **10**) so as to form a curved guide at the distal end of the instrument for receiving the looped suture wire as it returns to the distal end of the instrument.

Wire cutting mechanism **206** comprises a cutting bar **246** (FIGS. **8**, **12** and **14–16**). The distal end of cutting bar **246** is disposed in the aforementioned cutting bar channel **232** (FIG. **12**) and the proximal end of cutting bar **246** protrudes from the proximal end **212** of tube **208** (FIG. **8**).

The distal end of cutting bar **246** (FIGS. **12**, and **14–16**) preferably comprises a plurality of distinct faces, i.e., a cutting face **248** defining a cutting edge **250**, a relief face **252** set at an angle α to cutting face **248**, an ejection ramp face **254**, and an ejection push face **258**. As will hereinafter be discussed in further detail, when cutting bar **246** is driven distally so as to encounter suture wire extending between second channel **228** and third channel **230** (and hence across cutting bar channel **232**), cutting edge **250** will sever the suture wire, ejection ramp face **254** will lift the trailing end of the severed suture wire out of cutting bar channel **232** and up over island **236** so that the loop may be released from the distal end of the suturing instrument, and ejection push face **258** will push the suture loop free from the distal end of suturing instrument **2**.

The proximal end of cutting bar **246** comprises a pusher element **260** (FIGS. **2** and **8**) adapted to be engaged by lever **104** when cannula assembly **200** is mounted to handle assembly **100** and lever **104** is pulled toward handle **102**, whereby to move cutting bar **246** distally within cannula assembly **200**. A compression spring **262** is located between pusher element **260** and mount **214** so as to bias cutting bar **246** proximally. As will hereinafter be discussed in further detail, the operations of lever **104** and wire cutting mechanism **206** are preferably coordinated with one another so that pusher element **260** is not engaged by lever **104** until the later part of the lever's stroke, so that advancement of the suture wire will have ceased by the time cutting bar **246** is activated.

Looking next at FIGS. **10**, **11** and **17**, fixed second portion **224** includes the second half of the aforementioned first channel **226** for receiving the distal end of the aforementioned wire supply cartridge **400**, the second half of the aforementioned cutting bar channel **232**, and a slot **264** which extends proximally from the distal end of the instrument. Slot **264** is sized so that when first fixed portion **222** is engaging second fixed portion **224**, a gap slightly wider than the diameter of the suture wire will be formed between the top of island **236** and the opposing material of fixed second portion **224**, in order to permit a formed loop of suture wire to be released from the end of the suturing instrument, as will also hereinafter be discussed in further detail. Slot **264** is configured so that the suture wire will be maintained in third channel **230** until after the suture wire has been cut and partially bent so as to keep the suture wire in position for proper cutting and bending.

Fixed first portion **222** and fixed second portion **224** are preferably formed out of material which is harder than the suture wire passing through channels **228** and **230**, so as to minimize wear on the instrument. In one preferred form of the invention, first fixed portion **222** and fixed second portion **224** are formed out of a carbide alloy.

Preferably a loading guide **268** (FIGS. **8**, **9** and **11**) is positioned in tube **208** between end effector **204** and mount **214**, so as to provide guidance and support for cutting bar **246** and the distal end of wire supply cartridge **400**.

In one preferred form of the invention, end effector **204** includes a recess **270** (FIGS. **12** and **17**) at its front end. Recess **270** permits soft tissue to protrude into the interior of end effector **204** (see FIG. **27**) and provides a pair of projections **272**, **274** for pressing into the tissue and stabilizing the suturing instrument thereagainst. If desired, one or both of the projections **272**, **274** can be made relatively sharp so as to enhance tissue engagement or manipulation of prosthetic material (e.g., surgical mesh), and/or one of the projections (e.g., projection **274**) can be made slightly longer than the other projection, so as to facilitate an oblique approach to a tissue surface (see, for example, FIG. **26**).

Wire Drive Assembly **300**

Looking next at FIGS. **4**, **5** and **18**–**21**, wire drive assembly **300** comprises a fixed block **302**, a movable block **304**, a first drive shaft roller **306** connected to a spur gear **308** via an axle **310** passing through fixed block **302** and a one way clutch **312**, and a second drive shaft roller **314** connected to a spur gear **316** via an axle **318** and a one way clutch **320**. A pair of capture blocks **322** and **324** rotatably capture drive shaft rollers **306** and **314** to blocks **302** and **304**, respectively.

Movable block **304** is slidably mounted to fixed block **302** via a pair of rods **326** and **328** that pass through movable block **304**, fixed block **302** and are secured to a cam follower **330**, with springs **332** and **334** biasing movable block **304** into engagement with fixed block **302**. A lever **336** and cam **338** are provided for manually forcing movable block **304** away from fixed block **302**, and hence drive shaft roller **314** away from drive shaft roller **306**, and hence spur gear **316** away from spur gear **308**.

Wire drive assembly **300** is normally disposed in handle assembly **100** so that spur gears **308** and **316** engage the teeth **118** of rack **114**, and so that drive shaft roller **314** is in substantial engagement with drive shaft roller **306**.

However, depressing lever **336** will cause cam follower **338** to pivot, whereby to force movable block **304** away from fixed block **302** and whereby to separate roller **314** from roller **306** (and to separate spur gear **316** from spur gear **308**). Wire supply cartridge **400** may then be inserted between rollers **314** and **306** and, by then restoring lever **336** to its inboard position, cause the suture wire to be gripped by rollers **306** and **314**, whereupon the suture wire may be driven by rollers **306** and **314** out the distal end of the suturing instrument.

More particularly, after a fresh wire supply cartridge **400** has been installed in the instrument, suture wire may be driven out the distal end of the instrument by depressing lever **104** toward handle **102**. Depressing lever **104** toward handle **102** causes roll pin **112** (FIG. **2**) to ride within slot **110**. More particularly, as the top end of lever **104** moves about pivot pin **108**, roll pin **112** moves through slot **110**. This causes rack **114** to move distally, which in turn causes spur gears **308** and **316** to rotate, which in turn causes rollers **306** and **314** to rotate, which in turn causes a length of suture wire to be advanced out the distal end of the suturing instrument.

As lever **104** continues to rotate, the toothless region of rack **114** (i.e., the smooth wall **120** at the proximal end of rack **114**) is advanced to spur gears **308** and **316**, whereby rotation of rollers **306** and **314** will cease and suture wire will no longer be advanced out the distal end of the suturing instrument. Thus it will be seen that by carefully regulating the length of the rack's teeth **118**, the length of suture wire ejected from the instrument can also be regulated.

Further movement of lever **104** will then cause the cutting bar's pusher element **260** (FIG. **2**) to be engaged, whereby cutting bar **246** will be advanced distally so as to sever the formed loop of suture wire from the suture wire remaining in the instrument, lift the trailing end of the suture loop over island **236** and then push the suture loop free from the suturing instrument.

At the completion of the stroke, lever **104** is released, thereby allowing the aforementioned parts to return to their starting position under the influence of spring **116**. However, one way clutches **312** and **320** (FIG. **19**) interposed between drive rollers **306** and **314**, and the drive rollers **306** and **314**, respectively, prevent reverse movement of the drive rollers, thereby preventing any retraction of the suture wire.

Thus, a single throw of lever **104** will result in a predetermined degree of movement of drive rollers **306** and **314**, which will in turn result in a pre-determined length of suture wire being advanced out of the distal end of the suturing instrument.

It should be appreciated that each drive roller and axle assembly (i.e., drive roller **306** and axle **310**, and drive roller **314** and axle **318**) is preferably machined (i.e., turned) from a single, continuous piece of metal, using the same tool setup, so that the alignment of both is immune from the inaccuracies which might occur if they were turned at different occasions and assembled using holes and holding means. This construction is important, because the drive rollers are approximately 30 times the diameter of the suture wire they are driving and even the slightest alignment inaccuracies can rotate the wire as it is moved forward. Since the wire is permanently curved by the exit path in the end effector **204**, any such wire rotation may cause the wire to swerve from its normal trajectory from the end effector and possibly prevent the leading tip of the wire from properly returning to the end effector after it has passed through the subject.

It should also be appreciated that peripheral grooves may be formed in drive rollers **306** and **314**. Such grooves provide a seat for the suture wire being driven and help increase the surface area contact between the drive rollers and the suture wire.

Wire Supply Cartridge **400**

Looking next at FIGS. **22**–**25**, wire supply cartridge **400** generally comprises a spool housing **402**, a wire spool **404**, a spool retainer spring **406**, a spool cover **408**, a molded tube support **410** and a wire support tube **412**. A length of suture wire **416** extends from spool **404** and through molded tube support **410** and wire support tube **412**.

More particularly, a supply coil of suture wire **416** (comprising wire formed of metal or any other suitable material having the required flexibility and stiffness) may be supplied in the base of cartridge **400** and is fed into wire support tube **412**. Wire support tube **412** surrounds suture wire **416** from spool housing **402** to the distal end of suturing instrument **2** where, with the distal end of wire support tube **412** received in channel **226** (FIG. **12**), the suture wire enters second channel **228** in end effector **204**. Wire support tube **412** ensures that suture wire **416** does not bend or buckle as the suture wire is pushed through handle assembly **100** and cannula assembly **200**. More particularly, wire support tube **412** preferably forms a sufficiently close sliding fit with suture wire **416** such that suture wire **416** cannot bend or buckle as the suture wire is advanced through suturing instrument **2**. At the same time, wire support tube **412** is also formed so as to present a minimum of friction to suture wire **416** as the suture wire is advanced through the instrument. The foregoing characteristics are important, inasmuch as suture wire **416** is extremely thin and flexible and highly susceptible to bending or buckling in the absence of some sort of lateral support.

By way of example but not limitation, where suture wire **416** is formed out of stainless steel and has a diameter of 0.017 inch, wire support tube **412** might have an inside diameter of 0.185 inch and an outside diameter of 0.050 inch. In addition, wire support tube **412** is preferably formed out of 316 stainless steel, however, it may alternatively be formed out of some other material. If desired, the interior of wire support tube **412** may be coated with a lubricant so as to facilitate closely-supported, low-friction passage of the suture wire through the wire support tube.

Wire support tube **412** and its surrounding molded tube support **410** have aligned openings **418** and **420**, respectively, on opposite sides thereof. Openings **418** and **420** expose diametrically opposed portions of the suture wire **416** so that rollers **306** and **314** may contact suture wire **416** and urge the suture wire forward toward the distal end of suturing instrument **2**, as will hereinafter be discussed in further detail.

As noted above, wire supply cartridge **400** may be loaded into wire drive assembly **300** by actuating lever **336** so as to force movable block **304** away from fixed block **302** and thereby separate rollers **306** and **314**. Once roller **314** is separated from roller **306** by a sufficient distance, wire support tube **412** may be inserted between rollers **306** and **314**, and then roller **314** returned towards roller **306** such that rollers **306** and **314** contact either side of suture wire **416** through the aligned openings **418** and **420** formed in either side of wire support tube **412** and its surrounding molded support tube **410**, respectively.

Operation

Suturing instrument **2** may be used to apply loops **422** (FIG. **26**) of wire suture **416** to a subject so as to effect a desired suturing operation.

By way of example but not limitation, and looking now at FIGS. **26**–**33**, suturing instrument **2** may be used to suture together two portions **500**, **502** of a subject which is to be sutured. In a typical case, portions **500**, **502** might comprise two sections of severed tissue which need to be re-attached to one another, or two pieces of previously unattached tissue which need to be attached to one another. However, one or the other of the portions **500**, **502** might also comprise artificial mesh or some other object which is to be attached to tissue, etc. (e.g., it might comprise "hernia mesh" of the sort attached to the interior of the abdominal wall during hernia repair surgery). In addition, in a typical case, portions **500**, **502** might be located relatively deep within a patient, and might be accessed during an endoscopic or a so-called "minimally invasive" or a so-called "closed surgery", procedure; however, in other circumstances, portions **500**, **502** might be accessed during a conventional, or so-called "open surgery", procedure. This latter situation might include procedures done at the outer surface of the patient's body, i.e., where portions **500**, **502** comprise surface elements.

In any case, suturing instrument **2** is initially prepared for use by installing a wire supply cartridge **400** into the suturing instrument, if a cartridge **400** is not yet installed. As noted above, wire supply cartridge **400** is installed in suturing instrument **2** by (1) removing shroud **126**, (2) moving the wire drive assembly's release lever **336** to its open position, so as to move rollers **306** and **314** apart; (3) passing the distal end of the cartridge (i.e., the distal end of wire support tube **412**) through wire drive assembly **300** and cannula assembly **200** until the distal end of wire support tube **412** is located in the end effector's first channel **226**, at which point the cartridge's molded tube support **410** will be positioned intermediate rollers **306** and **314**; and (4) moving the wire drive assembly's release lever **336** back to its closed position, so that rollers **306** and **314** engage the suture wire **416** through openings **420** and **418**, and so that spur gears **308** and **316** engage the teeth **118** of rack **114**.

At this point suturing instrument **2** will be ready for use.

When suturing instrument **2** is to apply a suture loop **422** to a subject, the distal end of the suturing instrument is positioned against the subject, e.g., it is positioned against portions **500**, **502** (FIGS. **26** and **27**).

Once the distal end of suturing instrument **2** has been placed against subject portions **500**, **502**, lever **104** is pulled back against handle **102**. As the top end of lever **104** moves distally, rack **114** is also moved distally, whereby rack teeth **118** will cause spur gears **308** and **316**, and hence rollers **306** and **314**, to rotate. Rotation of rollers **306** and **314** in turn causes suture wire **416** to advance out of the distal end of wire support tube **412** (FIG. **27**). The suture wire advances down second channel **228**, across cutter bar channel **232** (FIG. **28**), through second channel **230** and then out of the instrument (FIG. **29**). Due to the curved geometry of channel **230**, the suture wire emerging from end effector **204** will take on a set, causing it to curl in a loop fashion, whereby the suture wire will pass through the material to be sutured and then back into slot **264** in the end effector's fixed second portion **224** (FIG. **30**). To assist the returning wire into slot **264**, the guide surface **244** may be provided at the distal end of end effector **204**.

If desired, the proximal end **276** (FIG. **17**) of slot **264** in the end effector's fixed second portion **224** can act as a sort of deflecting anvil to receive and redirect the suture wire **416** received from third channel **230**. In such a case, slot **264** actually helps form loop **422**. However, in accordance with the present invention, it is not necessary for slot **264** to act as a deflecting anvil for suture wire **416**, since the curvature of loop **422** can be imparted solely by the geometry of third channel **230** if desired.

Suture wire **416** is advanced a predetermined amount, i.e., the correct amount to form the desired loop construct. In other words, where a "Q-form loop" **422** is to be formed, suture wire **416** is advanced so that the leading end **424** (FIG. **30**) of the suture wire passes across cutting bar passageway **232** (FIG. **31**) and back out of the instrument until the leading end **424** of the suture wire is intermediate the front end of the tool (FIG. **32**). At this point the advancement of suture wire **416** is stopped.

As noted above, in the preferred embodiment of the invention, the length of suture wire advanced out of the distal end of the instrument is regulated by the length of the teeth **118** placed on rack **114**. More particularly, the initial movement of lever **104** toward handle **102** causes the toothed portion **118** of rack **114** to move past spur gears **308** and **316**, whereby to rotate drive rollers **306** and **314** and hence advance suture wire **416**. Further movement of lever **104** toward handle **102** causes the smooth wall **120** of rack **114** to move past spur gears **308** and **316**, which results in no movement of spur gears **308** and **316** and hence no advancement of suture wire **416**. Thus, the length of toothed portion **118** of rack **114** regulates the extent of suture wire drive.

However, in accordance with the present invention, continued movement of lever **104** toward handle **102** causes the distal end of the lever to engage the proximal end **260** of the cutting bar **246**, whereby to drive the cutting bar distally (FIG. **32**). This causes the cutting bar **246** to (i) first encounter, and then sever, the proximalmost portion **426** of the suture wire extending across cutting bar passageway **232**, whereby to separate loop **422** from the remainder of the suture wire carried by the suturing tool, and (ii) then drive against the end **426** of loop **422** whereby, with the assistance of island **236**, to bend the end **426** toward the material being joined.

Significantly, at the same time that this bending is occurring, inasmuch as cutting bar **246** includes ejection ramp face **254** and ejection push face **258** at the distal end thereof, and inasmuch as the end effector's fixed second portion **224** includes the slot **264** to form a gap in the end of the end effector, distal movement of cutting bar **246** will also serve to lift loop **422** up over island **236** and push it free from the suturing instrument, whereby to disengage the formed loop **422** from the distal end of suturing instrument **2**. Furthermore, if desired, cutting bar channel **232** may be offset from the plane of wire channels **228** and **232** so as to further assist lifting loop **422** up over island **236**. In addition, if desired, island **236** may be formed so as to be mechanically retractable into the body of fixed first portion **222**, whereby to further facilitate disengagement of the formed loop **422** from the suturing instrument.

Due to the manner in which loop **422** is formed, the trailing end **426** of the loop will project distally, into the material being formed (FIG. **33**). This feature is generally highly desirable, since it produces a secure, low profile fixation.

Various factors can affect how the wire element loops in the tissue. These factors include instrument-related factors (e.g., the curvature of third channel **230**, etc.), wire-related factors (e.g., wire tensile strength, wire yield stress, wire diameter, etc.) and tissue-related factors (e.g., tissue density, tissue elasticity, tissue thickness, tissue stabilization, etc.).

The aforementioned factors are preferably taken into account when forming wire loops in tissue. For example, when forming a loop in intestine, which tends to be a relatively delicate tissue, it is generally preferable to use a relatively "soft" wire; correspondingly, when forming a loop in the abdominal wall, which tends to be a relatively tough tissue, it is generally preferable to use a relatively "hard" wire.

In general, it has been found that suture wire formed out of 316 LVM stainless steel, having a tensile strength of 230–260 kpsi and a diameter of about 0.006–0.019 inch, is advantageous in particular applications. In general, when forming suture loops with a diameter of about 0.140–0.165 inch, it has been found acceptable to provide third channel **230** with a radius of 0.050–0.075 inch.

It should be appreciated that the suture loop **422** can, if desired, have a diameter which exceeds the diameter of suturing instrument.

It should also be appreciated that, due to the fact that cannula assembly **200** can be dismounted from handle assembly **100**, a set of different cannula assemblies, each having different loop-forming characteristics, can be provided to the user for appropriate selection at the time of use.

In a similar fashion, due to the fact that wire supply cartridge **400** can be dismounted from suturing instrument **2**, a set of different wire supply cartridges, each having different suture wire characteristics (e.g., material, hardness, diameter, etc.) can be provided to the user for appropriate selection at the time of use.

If desired, loop **422** can be used to secure mesh **502** to tissue **500**, or to attach other objects to tissue, or to attach objects other than tissue together, etc. In this respect it should be appreciated that where the suturing instrument is to be used to secure mesh to tissue, and where end effector **204** is provided with stabilizing projections **272**, **274** (FIGS. **12** and **17**), projections **272**, **274** are preferably formed narrow enough and long enough to extend completely through the mesh and contact the underlying tissue.

In addition to the foregoing, in FIGS. **26–33**, suturing instrument **2** is shown securing one layer of material **502** to an underlying layer of material **500**. However, it should also be appreciated that other types of attachments may also be formed with suture loop **422**. Thus, for example, in FIG. **34** two portions **500**, **502** are shown being secured to one another in a so-called "end to end" configuration.

As noted above, channels **228** and **230** are positioned on opposing sides of cutting bar channel **232**, whereby a length of suture wire **416**, extending between channels **228** and **230**, may be severed by cutting bar **246**. In this respect it will be appreciated that the angle at which cutting bar channel **232** intersects channel **228** has a bearing on the angle imparted to the leading tip **424** of suture wire **416**. More particularly, in FIG. **35** it will be seen that cutting bar channel **232** intersects second channel **228** at the angle θ; as a result, the leading tip of suture wire **416** will also be set at the angle θ.

In general, when considered solely from the standpoint of tissue penetration, it is typically desirable that the angle θ be as small as possible, in order that the suture wire have the sharpest possible tip to facilitate tissue penetration. At the same time, however, it must also be appreciated that the leading tip of suture wire **416** must traverse the substantial curvature of third channel **230** and, if the angle θ is too small, the sharp leading tip of the suture wire will strike the wall of third channel **230** (FIG. **36**) and thereby become damaged and/or blunted. On the other hand, if the angle θ is increased, the heel of the tip will engage the wall of third channel **230** (FIG. **37**), thereby leaving the sharp tip of the suture wire undamaged. Thus, it is generally preferred that the angle θ be set so that the leading tip of suture wire **416** be formed as sharp as possible while still being able to traverse the curvature of third channel **230** without damage.

As noted above, suture loop **422** can be used to secure tissue to tissue, or to secure an inanimate object to tissue, or to secure an inanimate object to an inanimate object, etc. In this respect it should be appreciated that one anticipated application for suture loop **422** is to secure a prosthetic cardiac valve to a valve seat within the heart. See, for example, FIG. **38**, where suturing instrument **2** is shown securing a prosthetic cardiac valve **504** to vascular tissue **508** (in this respect it should be appreciated that in FIG. **38**, a portion of the vascular tissue **508** has been removed so as to illustrate how suture loops **422** penetrate a portion of cardiac valve **504**).

In the foregoing description, suture wire **416** is described as comprising an elongated length which is cut into specific lengths at the time of use by the action of cutting bar **246**. In this respect it should also be appreciated, however, that suture wire **416** may be pre-cut into selected lengths prior to use, and the pre-cut lengths then stored in a magazine or the like, for deployment at the time of use. In such a case, cutting bar **246** will act as a forming and ejecting tool rather than as a cutting, forming and ejecting tool.

As noted above, suture wire **416** may comprise a wire formed out of a metal or any other suitable material having the required flexibility and stiffness. By way of example but not limitation, suture wire **416** may comprise stainless steel, titanium, tantalum, etc.

If desired, suture wire **416** may also be coated with various active agents. For example, suture wire **416** may be coated with an anti-inflammatory agent, or an anti-coagulant agent, or an antibiotic, or a radioactive agent, etc.

Cannula Assembly 200A

In an alternative form of the invention, cannula assembly **200** may be replaced by a cannula assembly **200**A. Cannula assembly **200**A is substantially the same as cannula assembly **200** described above, except as will hereinafter be described. Cannula assembly **200**A is shown in greater detail in FIGS. **39** and **40**. Cannula assembly **200**A comprises shaft **202**, end effector **204**A and wire cutting mechanism **206**A.

Shaft **202** is substantially the same as the shaft **202** discussed above with respect to cannula assembly **200**.

End effector **204**A is secured to the distal end of shaft tube **202**.

End effector **204**A is configured so as to form a modified suture loop **422**A (FIG. **41**), sometimes referred to as a "modified suture clip" or a "modified Q-form loop" or a "Q-form clip", as will hereinafter be discussed.

More particularly, end effector **204**A comprises a fixed first portion **222**A (FIGS. **39** and **40**) and a fixed second portion **224**A.

As seen in FIGS. **42** and **43**, fixed first portion **222**A includes a first channel **226**A for receiving the distal end of the aforementioned wire supply cartridge **400**, a smaller diameter second channel **228**A for supporting suture wire as the suture wire emerges from wire supply cartridge **400**, and a third channel **230**A for receiving the suture wire after the suture wire passes by cutting bar channel **232**A and for imparting a selected curvature to the suture wire, whereby to form the suture loop, as will hereinafter be discussed in further detail. Second channel **228**A and third channel **230**A are coplanar. Third channel **230**A and cutting bar channel **232**A effectively form an island **236**A at the distal end of end effector **204**A.

In order to assist the controlled retention of suture wire during its travel within second channel **228**A and third channel **230**A, one or both of these channels may be given an undercut profile such as the dovetail profile **238**A shown in FIG. **43** with respect to third channel **230**A. At the same time, in order to minimize harmful friction between the suture wire and fixed first portion **222**A, second channel **230**A may be widened slightly at locations other than **240**A (FIG. **42**); locations **240**A are, for this particular clip form, the operative contact points for effecting wire bending (in this respect it should be appreciated that other particular clip forms may have other contact points).

In addition, in order to facilitate the release of a formed suture clip from the instrument, the proximal end of island **236**A may be relieved at **242**A (FIG. **42**), and the remaining portions of island **236**A may be radiused as shown at **243**A so as to facilitate the release of a formed suture clip from the instrument.

In addition to the foregoing, fixed first portion **222**A may be relieved as shown as **244**A (FIG. **43**) so as to form a curved guide at the distal end of the instrument for receiving the looped suture wire as it returns to the distal end of the instrument.

Wire cutting mechanism **206**A comprises a cutting bar **246**A (FIGS. **44**–**47**). The distal end of cutting bar **246**A is disposed in the aforementioned cutting bar channel **232**A and the proximal end of cutting bar **246**A protrudes from the proximal end **212** of tube **208** (FIG. **8**).

The distal end of cutting bar **246**A (FIGS. **43**–**46**) preferably comprises a plurality of distinct faces, i.e., a cutting face **248**A defining a cutting edge **250**A, a relief face **252**A set at an angle α to cutting face **248**A, and an ejection ramp face **254**A. When cutting bar **246**A is driven distally so as to encounter suture wire extending between second channel **228**A and third channel **230**A (and hence across cutting bar channel **232**A), cutting edge **250**A will sever the suture wire, ejection ramp face **254**A will, in conjunction with the island's relieved surface **242**A, lift the trailing end of the severed suture wire out of cutting bar channel **232**A and up over island **236**A so that the loop may be released from the distal end of the suturing instrument.

Looking next at FIGS. **39**, **40** and **48**, fixed second portion **224**A includes the second half of the aforementioned first channel **226**A for receiving the distal end of the aforementioned wire supply cartridge **400**, the second half of the aforementioned cutting bar channel **232**A, and a relief **264**A which extends proximally from the distal end of the instrument. Relief **264**A is sized so that when first fixed portion **222**A is engaging second fixed portion **224**A, third channel **230**A and island **236**A will be exposed, in order to permit a formed loop of suture wire to be released from the end of the suturing instrument.

Fixed first portion **222**A and fixed second portion **224**A are preferably formed out of material which is harder than the suture wire passing through channels **228**A and **230**A, so as to minimize wear on the instrument. In one preferred form of the invention, first fixed portion **222**A and fixed second portion **224**A are formed out of a carbide alloy.

In one preferred form of the invention, fixed first portion **222**A includes a recess **270**A (FIG. **39**) at its front end. Recess **270**A in fixed first portion **222**A and relief **264**A in fixed second portion **224**A together permit soft tissue to protrude into the interior of end effector **204**A. If desired, one or both of fixed first portion **222**A and/or fixed second portion **224**A can be relieved such as is shown at **271**A in FIG. **40** so as to facilitate engagement of the instrument with the material to be joined.

If desired, and looking now at FIGS. **29**–**56**, the floor **231**A of third channel **230**A may be inclined so as to move the looping suture wire out of the plane of second channel **228**A, whereby to facilitate forming the loop of suture wire. By way of example, the distal end of the floor **231**A can be inclined so as to move the looping suture wire out of the plane of the floor of second channel **228**A (see FIGS. **49**–**51**).

Wire Supply Cartridge **400**A

In an alternative form of the invention, wire supply cartridge **400** may be replaced by a wire supply cartridge **400**A. Looking next at FIGS. **52**–**55**, wire supply cartridge **400**A generally comprises a spool housing **402**, a wire spool **404**, a spool retainer spring **406**, a spool cover **408**, a molded tube support **410**A and a wire support tube **412**A. A length of suture wire **416** extends from spool **404** and through molded tube support **410**A and wire support tube **412**A.

More particularly, a supply coil of suture wire **416** (comprising wire formed of metal or any other suitable material having the required flexibility and stiffness) may be supplied in the base of cartridge **400**A and is fed into wire support tube **412**A. Wire support tube **412**A surrounds suture wire **416** from molded tube support **410**A to the distal end of suturing instrument **2** where, with the distal end of wire support tube **412**A received in channel **226** (FIG. **12**), the suture wire enters second channel **228** in end effector **204**. Wire support tube **412**A ensures that suture wire **416** does not bend or buckle as the suture wire is pushed through handle assembly **100** and cannula assembly **200**. More particularly, wire support tube **412**A preferably forms a sufficiently close sliding fit with suture wire **416** such that suture wire **416** cannot bend or buckle as the suture wire is advanced through suturing instrument **2**. At the same time, wire support tube **412**A is also formed so as to present a minimum of friction to suture wire **416** as the suture wire is advanced through the instrument. The foregoing characteristics are important, inasmuch as suture wire **416** is extremely thin and flexible and highly susceptible to bending or buckling in the absence of some sort of lateral support.

By way of example but not limitation, where suture wire **416** is formed out of stainless steel and has a diameter of 0.018 inch, wire support tube **412**A might have an inside diameter of 0.020 inch and an outside diameter of 0.050 inch. In addition, wire support tube **412**A is preferably formed out of **316** stainless steel, however, it may alternatively be formed out of some other material. If desired, the interior of wire support tube **412**A may be coated with a lubricant so as to facilitate closely-supported, low-friction passage of the suture wire through the wire support tube.

Wire support tube **412**A begins at an opening **418**A adjacent to an opening **420**A of molded tube support **410**A. Opening **420**A exposes diametrically opposed portions of the suture wire **416** so that rollers **306** and **314** may contact suture wire **416** and urge the suture wire forward toward the distal end of suturing instrument **2**, as hereinabove discussed in further detail.

As noted above, wire supply cartridge **400**A may be loaded into wire drive assembly **300** by actuating lever **336** so as to force movable block **304** away from fixed block **302** and thereby separate rollers **306** and **314**. Once roller **314** is separated from roller **306** by a sufficient distance, wire support tube **412**A may be inserted between rollers **306** and **314**, and then roller **314** returned towards roller **306** such that rollers **306** and **314** contact either side of suture wire **416** through the opening **420**A formed in molded support tube **410**A.

In other alternative forms of the invention (not shown), wire supply cartridge **400** may be replaced by a wire supply cartridge which does not include a spool retainer spring, and/or the wire supply may be provided as a coil within a housing and the spool itself omitted.

ADDITIONAL EMBODIMENT

Looking next at FIGS. **56**–**61**, there is shown a suturing instrument **2**B which comprises another preferred form of the present invention. Suturing instrument **2**B is particularly well suited for use as a disposable instrument, although it may also be used as a reusable instrument, and generally comprises a handle assembly **100**B, a cannula assembly **200**B, a wire drive assembly **300**B, and a wire supply **400**B, as will hereinafter be described in further detail.

Handle assembly **100**B generally comprises a handle **102**B and a lever **104**B. Handle **102**B is fixedly connected to the housing **106**B, and lever **104**B is pivotally connected to housing **106**B by the pivot pin **108**B. A stop **109**B limits counterclockwise (as seen from the angle of view of FIG. **56**) motion of lever **104**B, and a stop **111**B limits clockwise (as seen from angle of view of FIG. **56**) motion of lever **104**B. A pivot arm **113**B is pivotally connected to housing **106**B by a pivot pin **115**B. A stop **117**B limits counterclockwise (as seen from the angle of view of FIG. **56**) motion of pivot arm **113**B. A spring **119**B is connected between the proximal end of housing **106**B and pivot arm **113**B, and a spring **121**B is connected between pivot arm **113**B and lever **104**B, whereby pivot arm **113**B and lever **104**B are normally biased in a clockwise (as seen from the angle of view of FIG. **56**) direction, with lever **104**B resting against stop **111**B.

Cannula assembly **200**B comprises shaft **202**, end effector **204** or **204**A, and a wire cutting mechanism **206**B. To the extent not otherwise described, shaft **202**, end effector **204** or **204**A, and wire cutting mechanism **206**B are generally configured and/or function in the manner previously described. In this respect it should be noted that the wire cutting mechanism **206**B comprises the cutting bar **246**B. The distal end of cutting bar **246**B is generally similar to the distal end of cutting bar **246** or **246**A. The proximal end of cutting bar **246**B includes a flange **247**B. A spring **249**B is positioned coaxially around the proximal end of cutting bar **246**B and extends between flange **247**B and the distal end of housing **106**B, whereby to bias cutting bar **246**B proximally.

Wire drive assembly **300**B comprises a push rod **301**B which has its proximal end connected to pivot arm **113**B and its distal end connected to a sliding cage **303**B. Sliding cage **303**B includes a window **305**B having a camming surface **307**B formed therein. A puck or disc **309**B is slidably positioned within window **305**B so as to rest against camming surface **307**B. A spring **311**B biases puck **309**B proximally. As a result of this construction, when push rod **301**B advances sliding cage **303**B distally within shaft **202**, puck **309**B will ride proximally along camming surface **307**B so that the puck moves into secure engagement with the suture wire **416** extending through shaft **202**, whereby to advance suture wire **416** distally. However, when push rod **301**B retracts sliding cage **303**B proximally within shaft **302**, spring **311**B will yield so that puck **309**B can ride distally along camming surface **307**B so that the puck moves out of driving engagement with the suture wire **416** extending through shaft **202**, thus imparting stationary no motion to suture wire **416** during the cage's return stroke.

Wire drive assembly **300**B also comprises a stationary cage **313**B disposed near the distal end of shaft **202**, adjacent to end effector **204** or **204**A. Stationary cage **313**B includes a window **315**B having a camming surface **317**B formed therein. A flexible finger **319**B (preferably formed out of a short length of wire) is secured to shaft **202** and extends through window **315**B. As a result of this construction, when sliding cage **303**B advances suture wire **416** distally, flexible finger **319**B will ride distally along camming surface **317**B, so that the flexible finger **319**B moves out of binding engagement with suture wire **416**, thereby allowing suture wire **416** to advance substantially unimpeded by stationary cage **313**B. However, when sliding cage **303**B is moved through its return stroke, any proximal movement of suture wire **416** will cause flexible finger **319**B to ride proximally along camming surface **317**B, so that the flexible finger moves into tighter engagement with suture wire **416** and prevents substantial proximal movement of the suture wire.

Thus it will be seen that sliding cage **303**B and stationary cage **313**B together act as a one-way wire advancement mechanism, permitting suture wire **416** to be advanced distally within shaft **202** in response to distal movement of push rod **301**B but preventing substantial proximal motion of suture wire **416** when push rod **301**B moves proximally.

Wire supply **400**B comprises a length of suture wire **416** disposed within shaft **202**.

Suturing instrument **200**B preferably operates as follows.

First, with suturing instrument **200**B in the condition shown in FIG. **56** (i.e., with lever **104**B set against stop **111**B and with a supply of suture wire **416** in shaft **202**), the distal end of the instrument is placed against the subject. Then the free end of lever **104**B is moved toward handle **102**B, causing lever **104**B to move counterclockwise. As this occurs, spring **121**B causes pivot arm **113**B to move counterclockwise, which in turn causes push rod **301**B to move distally. As push rod **301**B moves distally, it causes sliding cage **303**B to also move distally, whereby suture wire **416** is advanced distally.

Pivot arm **113**B rotates counterclockwise until it engages stop **117**B, whereupon distal movement of push rod **301**B ceases, thus halting advancement of suture wire **416**. See FIGS. **58** and **59**. This distal advancement of suture wire **416** is sufficient to form the suture loop **422** (if the instrument's end effector is the end effector **204** described above) or the suture loop **422**A (if the instrument's end effector is the end effector **204**A described above).

However, even as pivot arm **113**B engages stop **117**B, lever **104**B is free to continue rotating in a counterclockwise direction, whereupon it engages flange **247**B on the distal end of cutting bar **246**B, thereby driving cutting bar **246**B distally. This motion continues until lever **104**B engages stop **109**B, whereupon distal movement of cutting bar **246**B ceases. See FIGS. **60** and **61**. This distal movement of cutting bar **246**B is sufficient to sever the formed suture loop (**422** or **422**A) from the remainder of the suture wire **416** and eject the formed suture loop from the instrument.

At this point lever **104**B is released, whereupon springs **119**B, **121**B, and **249**B return the instrument to the condition shown in FIG. **56**. As this occurs, stationary cage **313**B will prevent suture wire **416** from being retracted within shaft **202**, due to the cammed engagement of flexible finger **319**B with suture wire **416**.

Thereafter, the foregoing process may be repeated, until the desired number of suture loops has been deployed or until the supply of suture wire **416** is exhausted.

FIGS. **62**–**64** show a similar wire drive assembly **300**B, except that the sliding cage **303**B is configured to have its puck or disc **309**B released from wire engagement at the end of its stroke, rather than upon the retraction of sliding cage **303**B (as with the embodiment shown in FIGS. **56**–**61**).

More particularly, with the construction shown in FIGS. **62**–**64**, the sliding cage **303**B has a bottom groove **351**B (FIG. **64**) which receives a tongue **353**B (FIG. **64**) when the sliding cage **303**B advances from its retracted position (FIG. **62**) to its extended position (FIG. **63**). Sliding cage **303**B also includes a release lever **355**B that pivots about a pin **357**B. When the sliding cage **303**B is in its retracted position (FIG. **62**), release lever **355**B is withdrawn from puck or disc **309**B, and spring **311**B and camming surface **307**B keep puck **309**B engaged with suture wire **416** during the drive stroke. However, at the end of the drive stroke, tongue **353**B will enter bottom groove **351**B and cause release lever **355**B to pivot, whereby to move puck **309**B forward against the bias of spring **311**B, and thus move puck **309**B out of driving engagement with suture wire **416**. When the sliding cage **303**B is thereafter returned to its retracted position, a stop **359**B will cause release lever **355**B to return to its starting position, ready for another drive stroke.

MODIFICATIONS

It will be appreciated by those skilled in the art that numerous modifications and variations may be made to the above-disclosed embodiments without departing from the spirit and scope of the present invention.

Thus, for example, shaft **202** has been shown as being substantially straight; however, it is also anticipated that shaft **202** may be curved along its length. Furthermore, shaft **202** may be substantially rigid, or it may be flexible so that it can be bent along its length. It is also possible to form shaft **202** so that it has two or more articulating sections so as to aid in the positioning of end effector **204**.

Furthermore, with respect to suturing instrument **2**B shown in FIGS. **56**–**61**, sliding cage **303**B and/or stationary cage **313**B may be located within housing **106**B rather than within shaft **202**. Such a construction may be particularly advantageous where suturing instrument **2**B is intended to be reusable.

Also, with respect to suturing instrument **2**B shown in FIGS. **56**–**61**, a ratchet mechanism (e.g., similar to the ratchet mechanism **122**, **124** shown in FIG. **3**) may be incorporated into the device so as to ensure a complete suture loop **422** or **422**A is formed and released before another suture loop **422** or **422**A is begun.

What is claimed is:

1. A suturing instrument comprising:

a handle;

a shaft extending from the handle and having a proximal end and a distal end including an opening;

a first channel adapted to guide a suture wire in movement toward the opening;

a second channel extending from the first channel and shaped to impart a curvature to the suture wire as the suture wire moves in the second channel;

a cutter adapted to cut the suture wire; and

a wire drive located near the distal end of the shaft that is adapted to engage with and move the suture wire in the second channel;

wherein the suture wire forms a wire loop suture when moved out of the opening.

2. The instrument of claim **1**, wherein the wire drive is adapted to engage with a side of the suture wire to move the suture wire in the second channel.

3. The instrument of claim **1**, wherein the wire drive includes a cam and cam follower adapted to cooperate to engage the suture wire.

4. The instrument of claim **3**, wherein the cam includes a body having a sloped surface and the cam follower includes a disc that is movable along the sloped surface to engage with the suture wire.

5. The instrument of claim **1**, wherein the wire drive is located within the shaft.

6. The instrument of claim **1**, wherein the wire drive includes an element adapted to engage with the suture wire to resist proximal movement of the suture wire.

7. The instrument of claim **6**, wherein the element is adapted to engage with the suture wire to resist proximal movement of the suture wire when a portion of the wire drive moves proximally so as to re-engage the suture wire at a proximal position.

8. The instrument of claim **7**, wherein the element is adapted to disengage from the suture wire when the portion of the wire drive re-engages with the suture wire to move the suture wire distally.

9. The instrument of claim **1**, wherein the cutter includes a drive tube that extends along a portion of the shaft, and wherein the wire drive is at least partially located within the drive tube.

10. The instrument of claim **1**, wherein the second channel and the opening are arranged so that the suture wire extends in a generally distal direction upon exiting the opening.

11. The instrument of claim **1**, wherein when the wire drive moves the suture wire in the second channel, a free end of the suture wire moves from the opening and follows a curved path so that the free end moves back toward the instrument.

12. The instrument of claim **1**, wherein the wire drive is adapted to move the suture wire from the opening with force sufficient so that a free end of the suture wire can penetrate tissue.

13. The instrument of claim **1**, adapted to form an approximately circular wire loop suture by suture wire that is driven out of the opening in the distal end.

14. The instrument of claim **13**, adapted to form the wire loop suture at an extreme axial end of the shaft.

15. The instrument of claim **1**, wherein the cutter is adapted to cut the suture wire so as to form a sharp point on the suture wire.

16. The instrument of claim **15**, wherein the cutter is adapted to cut the suture wire to free a length of the suture wire from the instrument after at least a portion of the length of suture wire has passed through the second channel.

17. The instrument of claim **1**, wherein the cutter is adapted to cooperate with a portion of the second channel to cut the suture wire.

18. The instrument of claim **1**, wherein the cutter includes a cutting surface adapted to move distally along the shaft to cut the suture wire.

19. The instrument of claim **1**, wherein the cutter includes a cutting bar adapted to move distally to cut the suture wire.

20. The instrument of claim **1**, wherein the cutter is adapted to cut the suture wire so that a formed wire loop suture is freed from suture wire remaining attached to the instrument.

21. The instrument of claim **1**, wherein the wire drive is adapted to move the suture wire in an axial direction within the shaft.

22. The instrument of claim **1**, wherein the second channel includes an "S" shaped portion with a convex portion and a concave portion.

23. The instrument of claim **22**, wherein the cutter is adapted to cut the suture wire at a location between the convex portion and the concave portion.

24. The instrument of claim **1**, further comprising:

a continuous length of suture wire, wherein the instrument is adapted to form a plurality of wire loop sutures from the continuous length of suture wire.

25. The instrument of claim **1**, adapted for use in a minimally invasive surgical procedure.

26. The instrument of claim **1**, wherein the distal end includes an angled end face.

27. The instrument of claim **26**, arranged to form a wire loop suture in tissue by positioning the angled end face adjacent the tissue and driving the suture wire through the second channel such that a free end of the suture wire penetrates the tissue and follows a loop-like trajectory.

28. The instrument of claim **1**, further comprising:

a recessed portion at the distal end, the recessed portion adapted to receive tissue or material to be sutured.

29. The instrument of claim **28**, wherein the recessed portion includes a curved slot adapted to closely fit a portion of the suture wire that forms the wire loop suture.

30. The instrument of claim **29**, wherein the curved slot includes a scalloped surface adapted to guide a free end of suture wire into the curved slot.

31. The instrument of claim **28**, wherein the recessed portion includes a central slot and a pair of side recesses on opposite lateral sides of the central slot, and wherein the central slot is adapted to receive suture wire that is driven out of the opening to form the wire loop suture, and the pair of side recesses are adapted to receive portions of a pliable surface against which the distal end is placed.

32. The instrument of claim **1**, adapted to form, with the suture wire that moves out of the opening, the wire loop suture in a spiral shape having a leading end that is adjacent to a trailing portion of the suture wire.

33. The instrument of claim **1**, wherein the cutter is adapted to cut a trailing end of suture wire that forms the wire loop suture and to bend a portion of the trailing end inwardly toward a center of the loop.

34. A suturing instrument comprising:

a handle;

a shaft extending from the handle and having a proximal end and a distal end including an opening;

a first channel adapted to guide a suture wire in movement toward the opening;

a second channel extending from the first channel and shaped to impart a curvature to the suture wire as the suture wire moves in the second channel;

a cutter adapted to cut the suture wire; and

a wire drive including a cam and a cam follower arranged to cooperate to engage the suture wire, to move in a first direction to move the suture wire in the second channel, and to move in a second direction opposite the first direction, a portion of the wire drive biased toward engagement with the suture wire during movement in the second direction;

wherein the suture wire, when moved out of the opening, forms a wire loop suture.

35. The instrument of claim **34**, wherein the wire drive is adapted to engage with a side of the suture wire to move the suture wire in the second channel.

36. The instrument of claim **34**, wherein the cam follower is adapted to engage the suture wire.

37. The instrument of claim **36**, wherein the cam includes a body having a sloped surface and the cam follower includes a disc that is movable along the sloped surface to engage with the suture wire.

38. The instrument of claim **34**, wherein the cam and cam follower are located within the shaft.

39. The instrument of claim **34**, wherein the wire drive includes an element adapted to engage with the suture wire to resist proximal movement of the suture wire.

40. The instrument of claim **39**, wherein the element is adapted to engage with the suture wire to resist proximal movement of the suture wire when a portion of the wire drive moves proximally so as to re-engage the suture wire at a proximal position.

41. The instrument of claim **40**, wherein the element is adapted to disengage from the suture wire when the portion of the wire drive re-engages with the suture wire to move the suture wire distally.

42. The instrument of claim **34**, wherein the cutter includes a drive tube that extends along a portion of the shaft, and wherein the wire drive is at least partially located within the drive tube.

43. The instrument of claim **39**, wherein the element is biased toward engagement with the suture wire during movement in the second direction.

44. The instrument of claim **34**, wherein the second channel and the opening are arranged so that the suture wire extends in a generally distal direction upon exiting the opening.

45. The instrument of claim **34**, wherein when the wire drives moves the suture wire in the second channel, a free end of the suture wire moves from the opening and follows a curved path so that the free end moves back toward the instrument.

46. The instrument of claim **34**, wherein the wire drive is adapted to move the suture wire from the opening with force sufficient so that a free end of the suture wire can penetrate tissue.

47. The instrument of claim **34**, adapted to form an approximately circular wire loop suture by suture wire that is driven out of the opening in the distal end.

48. The instrument of claim **47**, adapted to form the wire loop suture at an extreme axial end of the shaft.

49. The instrument of claim **34**, wherein the cutter is adapted to cut the suture wire so as to form a sharp point on the suture wire.

50. The instrument of claim **49**, wherein the cutter is adapted to cut the suture wire to free a length of the suture wire from the instrument after at least a portion of the length of suture wire is passed through the second channel.

51. The instrument of claim **34**, wherein the cutter is adapted to cooperate with a portion of the second channel to cut the suture wire.

52. The instrument of claim **34**, wherein the cutter includes a cutting surface adapted to move distally along the shaft to cut the suture wire.

53. The instrument of claim **34**, wherein the cutter includes a cutting bar adapted to move distally to cut the suture wire.

54. The instrument of claim **34**, wherein the cutter is adapted to cut the suture wire so that a formed wire loop suture is freed from suture wire remaining attached to the instrument.

55. The instrument of claim **34**, wherein the wire drive is adapted to move the suture wire in an axial direction within the shaft.

56. The instrument of claim **34**, wherein the second channel includes an "S" shaped portion with a convex portion and a concave portion.

57. The instrument of claim **56**, wherein the cutter is adapted to cut the suture wire at a location between the convex portion and the concave portion.

58. The instrument of claim **34**, further comprising:

a continuous length of suture wire, wherein the instrument is adapted to form a plurality of wire loop sutures from the continuous length of suture wire.

59. The instrument of claim **34**, adapted for use in a minimally invasive surgical procedure.

60. The instrument of claim **34**, wherein the distal end includes an angled end face.

61. The instrument of claim **60**, arranged to form a wire loop suture in tissue by positioning the angled end face adjacent the tissue and driving the suture wire through the second channel such that a free end of the suture wire penetrates the tissue and follows a loop-like trajectory.

62. The instrument of claim **34**, further comprising:

a recessed portion at the distal end, the recessed portion adapted to receive tissue or material to be sutured.

63. The instrument of claim **62**, wherein the recessed portion includes a curved slot adapted to closely fit a portion of the suture wire that forms the wire loop suture.

64. The instrument of claim **63**, wherein the curved slot includes a scalloped surface adapted to guide a free end of suture wire into the curved slot.

65. The instrument of claim **62**, wherein the recessed portion includes a central slot and a pair of side recesses on opposite lateral sides of the central slot, and wherein the central slot is adapted to receive suture wire that is driven out of the opening to form the wire loop suture, and the pair of side recesses are adapted to receive portions of a pliable surface against which the distal end is placed.

66. The instrument of claim **34**, adapted to form, with the suture wire moved out of the opening, the wire loop suture in a spiral shape having a leading end that is adjacent to a trailing portion of the suture wire.

67. The instrument of claim **34**, wherein the cutter is adapted to cut the trailing end of suture wire that forms the wire loop suture and to bend a portion of the trailing end inwardly toward a center of the loop.

68. The instrument of claim **34**, wherein the cam follower of the wire drive is biased toward engagement with the suture wire during movement in the second direction.

69. The instrument of claim **68**, wherein the wire drive includes a spring that biases the cam follower toward engagement with the suture wire.

70. A suturing instrument comprising:

a handle;

a lever movably mounted to the handle;

a shaft extending from the handle and having a proximal end and a distal end including an opening;

a first channel adapted to guide a suture wire in movement toward the opening;

a second channel extending from the first channel and shaped to impart a curvature to the suture wire as the suture wire moves in the second channel;

a cutter adapted to cut the suture wire; and

a wire drive adapted to move the suture wire in the second channel;

wherein suture wire, when moved out of the opening, forms a wire loop suture, wherein movement of the lever in a first direction actuates the wire drive to move the suture wire in the second channel, and wherein the lever is linked to the wire drive so that the lever is also movable in the first direction without actuating the wire drive to move the suture wire.

71. The instrument of claim **70**, wherein movement of the lever in a first range of motion in the first direction actuates the wire drive to move the suture wire, and movement of the lever in a second range of motion in the first direction does not actuate the wire drive to move the suture wire.

72. The instrument of claim **71**, wherein movement of the lever in the second range of motion in the first direction actuates the cutter to cut the suture wire.

73. The instrument of claim **70**, wherein the lever is linked to the wire drive by a compliant member.

74. The instrument of claim **73**, wherein the compliant member includes a spring.

75. The instrument of claim **74**, wherein the handle includes a stop that when contacted by a portion of the wire drive prevents further actuation of the wire drive.

76. The instrument of claim **70**, wherein the wire drive is adapted to engage with a side of the suture wire to move the suture wire in the second channel.

77. The instrument of claim **70**, wherein the cutter includes a drive tube that extends along a portion of the shaft, and wherein the wire drive is at least partially located within the drive tube.

78. The instrument of claim **70**, wherein the second channel and the opening are arranged so that the suture wire extends in a generally distal direction upon exiting the opening.

79. The instrument of claim **70**, wherein when the wire drive moves the suture wire in the second channel, a free end of the suture wire moves from the opening and follows a curved path so that the free end moves back toward the instrument.

80. The instrument of claim **70**, wherein the wire drive is adapted to move the suture wire from the opening with force sufficient so that a free end of the suture wire can penetrate tissue.

81. The instrument of claim **70**, adapted to form an approximately circular wire loop suture by suture wire that is driven out of the opening in the distal end.

82. The instrument of claim **81**, adapted to form the wire loop suture at an extreme axial end of the shaft.

83. The instrument of claim **70**, wherein the cutter is adapted to cut the suture wire so as to form a sharp point on the suture wire.

84. The instrument of claim **70**, wherein the cutter is adapted to cut the suture wire to free a length of the suture wire from the instrument after the length of suture wire is passed through the second channel.

85. The instrument of claim **70**, wherein the cutter is adapted to cooperate with a portion of the second channel to cut the suture wire.

86. The instrument of claim **70**, wherein the cutter includes a cutting surface adapted to move distally along the shaft to cut the suture wire.

87. The instrument of claim **70**, wherein the cutter includes a cutting bar adapted to move distally to cut the suture wire.

88. The instrument of claim **70**, wherein the cutter is adapted to cut the suture wire so that a formed wire loop suture is freed from suture wire remaining attached to the instrument.

89. The instrument of claim **70**, wherein the wire drive is adapted to move the suture wire in an axial direction within the shaft.

90. The instrument of claim **70**, wherein the second channel includes an "S" shaped portion with a convex portion and a concave portion.

91. The instrument of claim **90**, wherein the cutter is adapted to cut the suture wire at a location between the convex portion and the concave portion.

92. The instrument of claim **70**, further comprising:

a continuous length of suture wire, wherein the instrument is adapted to form a plurality of wire loop sutures from the continuous length of suture wire.

93. The instrument of claim **70**, adapted for use in a minimally invasive surgical procedure.

94. The instrument of claim **70**, wherein the distal end includes an angled end face.

95. The instrument of claim **94**, wherein the instrument is arranged to form a wire loop suture in tissue by positioning the angled end face adjacent the tissue and driving the suture wire through the second channel such that a free end of the suture wire penetrates the tissue and follows a loop-like trajectory.

96. The instrument of claim **70**, further comprising:

a recessed portion at the distal end, the recessed portion adapted to receive tissue or material to be sutured.

97. The instrument of claim **96**, wherein the recessed portion includes a curved slot adapted to closely fit the portion of the suture wire when received in the curved slot.

98. The instrument of claim **97**, wherein the curved slot includes a scalloped surface adapted to guide a free end of suture wire into the curved slot.

99. The instrument of claim **96**, wherein the recessed portion includes a central slot and a pair of side recesses on opposite lateral sides of the central slot, and wherein the central slot is adapted to receive suture wire that is driven out of the opening to form the wire loop suture, and the pair of side recesses are adapted to receive portions of a pliable surface against which the distal end is placed.

100. The instrument of claim **70**, adapted to form, with the suture wire moved out of the opening, the wire loop suture in a spiral shape having a leading end that is adjacent to a trailing portion of the suture wire.

101. The instrument of claim **70**, wherein the cutter is adapted to both cut the trailing end of suture wire forming the wire loop suture and bend a portion of the trailing end inwardly toward a center of the wire loop suture.

102. A suturing instrument comprising:

a handle;

a lever movably mounted to the handle;

a shaft extending from the handle and having a proximal end and a distal end including an opening;

a first channel adapted to guide a suture wire in movement toward the opening;

a second channel extending from the first channel and shaped to impart a curvature to the suture wire as the suture wire moves in the second channel;

a cutter adapted to cut the suture wire; and

a wire drive adapted to move the suture wire in the second channel;

wherein suture wire moved out of the opening forms a wire loop suture, and wherein movement of the lever through a range of motion in a first direction actuates the wire drive to move the suture wire in the second channel and actuates the cutter to cut the suture wire such that one complete wire loop suture is formed and cut from suture wire remaining attached to the instrument.

103. The instrument of claim **102**, wherein movement of the lever in the first direction within a first portion of the range of motion actuates the wire drive to move the suture wire, and movement of the lever in the first direction within a second portion of the range of motion does not actuate the wire drive to move the suture wire.

104. The instrument of claim **103**, wherein movement of the lever in the second portion of the range of motion actuates the cutter to cut the suture wire.

105. The instrument of claim **102**, wherein the lever is linked to the wire drive by a compliant member.

106. The instrument of claim **105**, wherein the compliant member includes a spring.

107. The instrument of claim **106**, wherein the handle includes a stop that when contacted by a portion of the wire drive prevents further actuation of the wire drive.

108. The instrument of claim **102**, wherein the wire drive is adapted to engage with a side of the suture wire to move the suture wire in the second channel.

109. The instrument of claim **102**, wherein the cutter includes a drive tube that extends along a portion of the shaft, and wherein the wire drive is partially located within the drive tube.

110. The instrument of claim **102**, wherein the second channel and the opening are arranged so that the suture wire extends in a generally distal direction upon exiting the opening.

111. The instrument of claim **102**, wherein when the wire drive moves the suture wire in the second channel, a free end of the suture wire moves from the opening and follows a curved path so that the free end moves back toward the instrument.

112. The instrument of claim **102**, wherein the wire drive is adapted to move the suture wire from the opening with force sufficient so that a free end of the suture wire can penetrate tissue.

113. The instrument of claim **102**, adapted to form an approximately circular wire loop suture by suture wire that is driven out of the opening in the distal end.

114. The instrument of claim **113**, adapted to form the wire loop suture at an extreme axial end of the shaft.

115. The instrument of claim **102**, wherein the cutter is adapted to cut the suture wire so as to form a sharp point on the suture wire.

116. The instrument of claim **102**, wherein the cutter is adapted to cut the suture wire to free a length of suture wire from the instrument after the length of suture wire is passed through the second channel.

117. The instrument of claim **102**, wherein the cutter is adapted to cooperate with a portion of the second channel to cut the suture wire.

118. The instrument of claim **102**, wherein the cutter includes a cutting surface adapted to move distally along shaft to cut the suture wire.

119. The instrument of claim **102**, wherein the cutter includes a cutting bar adapted to move distally to cut the suture wire.

120. The instrument of claim **102**, wherein the cutter is adapted to cut the suture wire so that the formed wire loop suture is freed from suture wire remaining attached to the instrument.

121. The instrument of claim **102**, wherein the wire drive is adapted to move the suture wire in an axial direction within shaft.

122. The instrument of claim **102**, wherein the second channel includes an "S" shaped portion with a convex portion and a concave portion.

123. The instrument of claim **122**, wherein the cutter is adapted to cut the suture wire at a location between the convex portion and the concave portion.

124. The instrument of claim **102**, further comprising:

a continuous length of suture wire, wherein the instrument is adapted to form a plurality of wire loops sutures from the continuous length of suture wire.

125. The instrument of claim **102**, adapted for use in a minimally invasive surgical procedure.

126. The instrument of claim **102**, wherein the distal end includes an angled end face.

127. The instrument of claim **126**, arranged to form the wire loop suture in tissue by positioning the angled end face adjacent the tissue and driving the suture wire through the second channel such that a free end of the suture wire penetrates the tissue and follows a loop-like trajectory.

128. The instrument of claim **102**, further comprising:

a recessed portion at the distal end, the recessed portion adapted to receive tissue or material to be sutured.

129. The instrument of claim **128**, wherein the recessed portion includes a curved slot adapted to closely fit the portion of the suture wire when received in the curved slot.

130. The instrument of claim **129**, wherein the curved slot includes a scalloped surface adapted to guide a free end of suture wire into the curved slot.

131. The instrument of claim **128**, wherein the recessed portion includes a central slot and a pair of side recesses on opposite lateral sides of the central slot, and wherein the central slot is adapted to receive suture wire that is driven out of the opening, and the pair of side recesses are adapted to receive portions of a pliable surface against which the distal end is placed.

132. The instrument of claim **102**, adapted to form the wire loop suture in a spiral shape having a leading end that is adjacent to a trailing portion of the suture wire.

133. The instrument of claim **102**, wherein the cutter is adapted to both cut the trailing end of suture wire forming the wire loop suture and bend a portion of the trailing end inwardly toward a center of the wire loop suture.

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